



Clinical trial results:

A Phase 1b (Open-Label) / Phase 2 (Randomized, Double-Blinded) Study Evaluating Gemcitabine and Docetaxel With or Without Olaratumab in the Treatment of Advanced Soft Tissue Sarcoma

Summary

EudraCT number	2015-001316-34
Trial protocol	HU ES DE PL GB IT
Global end of trial date	

Results information

Result version number	v1
This version publication date	11 August 2021
First version publication date	11 August 2021

Trial information

Trial identification

Sponsor protocol code	I5B-MC-JGDL
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02659020
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15839

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	28 July 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 July 2020
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the safety and efficacy of two anti-cancer drugs (gemcitabine and docetaxel) with and without the study drug known as olaratumab in participants with advanced soft tissue sarcoma (STS) or STS that has spread to another part(s) of the body.

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	02 March 2016
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	Hungary: 11
Country: Number of subjects enrolled	United States: 161
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	United Kingdom: 31
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Israel: 18
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	Australia: 9
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Spain: 37
Worldwide total number of subjects	310
EEA total number of subjects	91

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)	227
From 65 to 84 years	83
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

Blinding implementation details:

Phase 1b (Open-Label), Phase 2 (Double-Blinded)

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel

Arm description:

Participants received intravenous infusions of olaratumab 15 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m²) on days 1, 8 plus docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207,IMC-3G3
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of olaratumab 15 mg/kg on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	LY188011,Gemzar
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of gemcitabine 900 mg/m² on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

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

Dosage and administration details:

Intravenous infusions of docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Arm title	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel
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Arm description:

Participants received intravenous infusions of olaratumab 20 mg/kg on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207,IMC-3G3
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of olaratumab 20 mg/kg on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	LY188011,Gemzar
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of gemcitabine 900 mg/m² on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

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

Dosage and administration details:

Intravenous infusions of docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Arm title	Phase1b:Cohort2Expand:20mg/kgOlaratumab+Gemcitabine+Docetaxel
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Arm description:

Following a protocol amendment, additional participants were enrolled into this group to confirm the safety of the 20 mg/kg dose level prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m²) on days 1, 8 plus docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207,IMC-3G3
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of olaratumab 20 mg/kg on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	LY188011,Gemzar
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of gemcitabine 900 mg/m² on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Intravenous infusions of docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Arm title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)
Arm description:	
This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207,IMC-3G3
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	LY188011,Gemzar
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Intravenous infusions of gemcitabine 900 mg/m ² on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Intravenous infusions of docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Arm title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)
Arm description:	
This cohort included participants who received commercially available olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Arm type	Experimental
Investigational medicinal product name	Olaratumab
Investigational medicinal product code	
Other name	LY3012207,IMC-3G3
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	LY188011,Gemzar
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of gemcitabine 900 mg/m² on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

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

Dosage and administration details:

Intravenous infusions of docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Arm title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
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Arm description:

This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria 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 infusions of placebo on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	LY188011,Gemzar
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of gemcitabine 900 mg/m² on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

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

Dosage and administration details:

Intravenous infusions of docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Arm title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
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Arm description:

This cohort included participants who received commercially available olaratumab prior to enrollment.

Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria 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 infusions of placebo on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	LY188011, Gemzar
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusions of gemcitabine 900 mg/m² on days 1, 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

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

Dosage and administration details:

Intravenous infusions of docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Number of subjects in period 1	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2Expanded: 20mg/kgOlaratumab+Gemcitabine+Docetaxel
Started	21	18	15
Received atLeast 1 Doseof Study Drug	21	18	15
Completed	15	11	10
Not completed	6	7	5
Consent withdrawn by subject	2	3	1
Physician decision	-	-	1
On Treatment	-	-	-
Adverse event, non-fatal	1	-	-
Progressive Disease	2	2	2
Lost to follow-up	1	2	1

Number of subjects in period 1	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)

Started	81	46	86
Received atLeast 1 Doseof Study Drug	81	45	86
Completed	51	26	58
Not completed	30	20	28
Consent withdrawn by subject	4	4	9
Physician decision	1	6	3
On Treatment	-	-	-
Adverse event, non-fatal	6	3	4
Progressive Disease	15	6	7
Lost to follow-up	4	1	5

Number of subjects in period 1	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Started	43
Received atLeast 1 Doseof Study Drug	43
Completed	28
Not completed	15
Consent withdrawn by subject	3
Physician decision	1
On Treatment	1
Adverse event, non-fatal	4
Progressive Disease	6
Lost to follow-up	-

Baseline characteristics

Reporting groups

Reporting group title	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel
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Reporting group description:

Participants received intravenous infusions of olaratumab 15 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m²) on days 1, 8 plus docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel
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Reporting group description:

Participants received intravenous infusions of olaratumab 20 mg/kg on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase1b:Cohort2Expand:20mg/kgOlaratumab+Gemcitabine+Docetaxel
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Reporting group description:

Following a protocol amendment, additional participants were enrolled into this group to confirm the safety of the 20 mg/kg dose level prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m²) on days 1, 8 plus docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)
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Reporting group description:

This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)
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Reporting group description:

This cohort included participants who received commercially available olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
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Reporting group description:

This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
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Reporting group description:

This cohort included participants who received commercially available olaratumab prior to enrollment. Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2Expand: 20mg/kgOlaratumab+Gemcitabine+Docetaxel
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Number of subjects	21	18	15
Age categorical			
Units: Subjects			
<65 years	20	12	6
>=65 years	1	6	9
<=18 years	0	0	0
Gender categorical			
Units: Subjects			
Female	11	8	7
Male	10	10	8
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	5	0	1
Not Hispanic or Latino	16	18	11
Unknown or Not Reported	0	0	3
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	0
White	15	10	13
More than one race	6	5	0
Unknown or Not Reported	0	0	0
Region of Enrollment			
Units: Subjects			
Hungary	0	0	0
United States	10	14	14
Poland	0	0	0
United Kingdom	0	0	0
Italy	0	0	0
Israel	0	0	0
France	0	0	0
Australia	0	0	1
Germany	0	0	0
Spain	11	4	0

Reporting group values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects	81	46	86
Age categorical			
Units: Subjects			
<65 years	66	27	66
>=65 years	15	19	20
<=18 years	0	0	0
Gender categorical			
Units: Subjects			
Female	48	28	58
Male	33	18	28

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	8	4	6
Not Hispanic or Latino	71	39	73
Unknown or Not Reported	2	3	7
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	2	2
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	1	8	1
White	61	30	70
More than one race	15	3	10
Unknown or Not Reported	1	2	3
Region of Enrollment			
Units: Subjects			
Hungary	5	0	6
United States	29	36	28
Poland	6	0	2
United Kingdom	11	3	12
Italy	2	0	4
Israel	4	3	7
France	2	0	3
Australia	6	0	2
Germany	7	4	11
Spain	9	0	11

Reporting group values	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)	Total	
Number of subjects	43	310	
Age categorical			
Units: Subjects			
<65 years	30	227	
>=65 years	13	83	
<=18 years	0	0	
Gender categorical			
Units: Subjects			
Female	28	188	
Male	15	122	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	4	28	
Not Hispanic or Latino	36	264	
Unknown or Not Reported	3	18	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	1	
Asian	2	11	

Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	2	14	
White	34	233	
More than one race	3	42	
Unknown or Not Reported	2	8	
Region of Enrollment			
Units: Subjects			
Hungary	0	11	
United States	30	161	
Poland	0	8	
United Kingdom	5	31	
Italy	0	6	
Israel	4	18	
France	0	5	
Australia	0	9	
Germany	2	24	
Spain	2	37	

End points

End points reporting groups

Reporting group title	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel
Reporting group description: Participants received intravenous infusions of olaratumab 15 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m ²) on days 1, 8 plus docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Reporting group title	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel
Reporting group description: Participants received intravenous infusions of olaratumab 20 mg/kg on days 1, 8 in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Reporting group title	Phase1b:Cohort2Expand:20mg/kgOlaratumab+Gemcitabine+D ocetaxel
Reporting group description: Following a protocol amendment, additional participants were enrolled into this group to confirm the safety of the 20 mg/kg dose level prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m ²) on days 1, 8 plus docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Reporting group title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab- naive)
Reporting group description: This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Reporting group title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)
Reporting group description: This cohort included participants who received commercially available olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Reporting group title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Reporting group description: This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Reporting group title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Reporting group description: This cohort included participants who received commercially available olaratumab prior to enrollment. Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.	
Subject analysis set title	Phase1b:Cohort2overall- 20mg/kgOlaratumab+Gemcitabine+Docetaxel
Subject analysis set type	Per protocol
Subject analysis set description: Participants received intravenous infusions of olaratumab 20 mg/kg on days 1, 8 in combination with gemcitabine 900 mg/m ² on days 1, 8 and docetaxel 75 mg/m ² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met (cohort 2).	

Following a protocol amendment, additional participants were enrolled into this group to confirm the safety of the 20 mg/kg dose level prior to opening the Phase 2 (cohort 2 expansion).

Subject analysis set title	Phase2:Olaratumab+Gemcitabine+Docetaxel
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met. This cohort is a combination of participants who never received olaratumab (olaratumab-naïve) and who received commercially available olaratumab (olaratumab pre-treated) prior to enrollment.

Subject analysis set title	Phase2:Placebo+Gemcitabine+Docetaxel
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met. This cohort is a combination of participants who never received olaratumab (olaratumab-naïve) and who received commercially available olaratumab (olaratumab pre-treated) prior to enrollment.

Subject analysis set title	Olaratumab + Gemcitabine + Docetaxel
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received intravenous infusions of olaratumab on days 1, 8 (phase 1: 15 or 20 mg/kg; phase 2: 20 mg/kg only in cycle 1 and 15 mg/kg in subsequent cycles) plus gemcitabine 900 mg/m² on days 1, 8 plus docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Primary: Phase 1b: Number of Participants with Dose Limiting Toxicity (DLT)

End point title	Phase 1b: Number of Participants with Dose Limiting Toxicity (DLT) ^{[1][2]}
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End point description:

A Dose Limiting Toxicity is defined as an Adverse Event (AE) that is likely related to the study medication or combination, and fulfils any one of the following criteria, graded according to the NCI-CTCAE Version 4.0:

1. Febrile neutropenia with documented Grade ≥ 3 infection or sepsis
2. Grade 4 neutropenia lasting 7 days or longer.
3. Grade 4 thrombocytopenia, or Grade 3 thrombocytopenia complicated by hemorrhage.
4. Nonhematologic Grade ≥ 3 toxicity, except for toxicities such as nausea, vomiting, transient electrolyte abnormalities, or diarrhoea that can be controlled with optimal medical management within 48 hours.

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

End point type	Primary
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End point timeframe:

Cycle 1 (Up To 21 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: Outcome reporting is only for Phase 1b participants.

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2Expand:20mg/kgOlaratumab+Gemcitabine+Docetaxel	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	18	15	
Units: participants	1	4	3	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Overall Survival (OS) (Olaratumab-Naive)

End point title	Phase 2: Overall Survival (OS) (Olaratumab-Naive) ^[3]
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End point description:

OS was defined as the time from the date of randomization to the date of death from any cause. For each participant who is not known to have died as of the data-inclusion cut-off date for a particular analysis, overall survival duration was censored for that analysis at the date of last prior contact.

Analysis Population Description: Phase 2: All randomized participants (including the censored participants). Number of participants censored in "Olaratumab+ Gemcitabine+Docetaxel(Olaratumab-naive)=30," "Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)=28."

End point type	Primary
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End point timeframe:

Baseline to Date of Death Due to Any Cause (Up To 38 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: Outcome reporting is only for Phase 2 Olaratumab-Naive participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	81	86		
Units: Months				
median (confidence interval 95%)	16.76 (15.28 to 25.40)	18.04 (13.17 to 22.90)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.775 ^[4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.945
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.639
upper limit	1.397

Notes:

[4] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and Eastern Cooperative Oncology Group Performance Status (ECOG PS) (0 vs1).

Secondary: Phase 1b: Pharmacokinetics (PK): Maximum Serum Concentration (Cmax) of Olaratumab

End point title	Phase 1b: Pharmacokinetics (PK): Maximum Serum Concentration (Cmax) of Olaratumab ^[5]
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End point description:

Cmax of Olaratumab.

Analysis Population Description: Phase 1b: All participants who received at least one dose of Olaratumab and had evaluable PK data.

End point type	Secondary
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End point timeframe:

Pre-dose, 5 minutes (min), 1, 4, 4.5, 24, 96, 168, 336 hours (h) post-dose on Cycle 1 Day 1, Cycle 1 Day 8, Cycle 3 Day 1, Cycle 3 Day 8

Notes:

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

Justification: Outcome reporting is only for Phase 1b participants.

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2overall-20mg/kgOlaratumab+Gemcitabine+Docetaxel		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20 ^[6]	33 ^[7]		
Units: micrograms per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 (Day 1)	432 (± 24)	572 (± 25)		
Cycle 1 (Day 8)	460 (± 25)	697 (± 20)		
Cycle 3 (Day 1)	523 (± 38)	644 (± 20)		
Cycle 3 (Day 8)	513 (± 21)	689 (± 20)		

Notes:

[6] - Cycle 1 (Day 1) = 19;
Cycle 3 (Day 1), Cycle 3 (Day 8) = 14

[7] - Cycle 3 (Day 1) = 23;
Cycle 3 (Day 8) = 22

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b: PK: Minimum Serum Concentration (Cmin) of Olaratumab

End point title	Phase 1b: PK: Minimum Serum Concentration (Cmin) of Olaratumab ^[8]
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End point description:
Cmin of Olaratumab.

Analysis Population Description: Phase 1b: All participants who received at least one dose of Olaratumab and had evaluable PK data.

End point type	Secondary
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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 8, Cycle 3 Day 1

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: Outcome reporting is only for Phase 1b participants.

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2overall- 20mg/kgOlaratumab+Gemcitabine+Docetaxel		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20 ^[9]	31 ^[10]		
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 (Day 1)	95.9 (± 37)	142 (± 38)		
Cycle 1 (Day 8)	64.3 (± 64)	93.3 (± 47)		
Cycle 3 (Day 1)	137 (± 40)	252 (± 36)		

Notes:

[9] - Cycle 1 (Day 8) = 19;
Cycle 3 (Day 1) = 14

[10] - Cycle 1 (Day 8) = 30;
Cycle 3 (Day 1) = 22

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b: PK: Elimination Half-Life (T1/2) of Olaratumab

End point title	Phase 1b: PK: Elimination Half-Life (T1/2) of Olaratumab ^[11]
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End point description:
T1/2 of Olaratumab.

Analysis Population Description: Phase 1b: All participants who received at least one dose of Olaratumab and had evaluable PK data.

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 8, Cycle 3 Day 1, Cycle 3 Day 8	

Notes:

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

Justification: Outcome reporting is only for Phase 1b participants.

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2overall: 20mg/kgOlaratumab+Gemcitabine+Docetaxel		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19 ^[12]	33 ^[13]		
Units: days				
geometric mean (geometric coefficient of variation)				
Cycle 1 (Day 1)	4.60 (± 34)	4.29 (± 28)		
Cycle 1 (Day 8)	6.25 (± 25)	6.62 (± 27)		
Cycle 3 (Day 1)	5.17 (± 36)	6.36 (± 41)		
Cycle 3 (Day 8)	5.82 (± 30)	6.39 (± 32)		

Notes:

[12] - Cycle 3 (Day 1), Cycle 3 (Day 8) = 14

[13] - Cycle 3 (Day 1) = 23;
Cycle 3 (Day 8) = 21

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b/2: PK: Cmax of Gemcitabine

End point title	Phase 1b/2: PK: Cmax of Gemcitabine ^[14]
End point description:	
Cmax of Gemcitabine.	

Analysis Population Description: Phase 1b/2: All participants who received at least one dose of Gemcitabine and had evaluable PK data.

End point type	Secondary
End point timeframe:	
Day 8 of Cycle 1 (end of infusion, 1, 2, 4, 24 hours post-infusion)	

Notes:

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

Justification: Outcomes were reported by combining phase 1b cohort 2+cohort2expand arms [i.e. Cohort2overall: 20mg/kgOlaratumab+Gemcitabine+Docetaxel]; Phase2Olaratumab+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2: Olaratumab+Gemcitabine+Docetaxel]; Phase2Placebo+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Placebo+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2: Placebo+Gemcitabine+Docetaxel]

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2overall-20mg/kgOlaratumab+Gemcitabine+Docetaxel	Phase2:Olaratumab+Gemcitabine+Docetaxel	Phase2:Placebo+Gemcitabine+Docetaxel
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	24	87	88
Units: µg/mL				
geometric mean (geometric coefficient of variation)	2.79 (± 70)	3.49 (± 50)	3.01 (± 122)	2.35 (± 105)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b/2: PK: Area Under the Concentration-Time Curve From Time Zero to Infinity (AUC[0-∞]) of Gemcitabine

End point title	Phase 1b/2: PK: Area Under the Concentration-Time Curve From Time Zero to Infinity (AUC[0-∞]) of Gemcitabine ^[15]
End point description: Phase 1b/2: Due to short half-life of Gemcitabine and sparse pharmacokinetic sampling employed, AUC[0-∞] couldn't be evaluated.	
End point type	Secondary
End point timeframe: Day 8 of Cycle 1 (end of infusion, 1, 2, 4, 24 hours post-infusion)	

Notes:

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

Justification: Outcomes were reported by combining phase 1b cohort 2+cohort2expand arms [i.e. Cohort2overall:20mg/kgOlaratumab+Gemcitabine+Docetaxel]; Phase2Olaratumab+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2: Olaratumab+Gemcitabine+Docetaxel]; Phase2Placebo+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Placebo+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2: Placebo+Gemcitabine+Docetaxel]

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2overall-20mg/kgOlaratumab+Gemcitabine+Docetaxel	Phase2:Olaratumab+Gemcitabine+Docetaxel	Phase2:Placebo+Gemcitabine+Docetaxel
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[16]	0 ^[17]	0 ^[18]	0 ^[19]
Units: nanograms*hours per milliliter				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[16] - Zero participants analysed due to short half-life of Gemcitabine and sparse pharmacokinetic sampling

[17] - Zero participants analysed due to short half-life of Gemcitabine and sparse pharmacokinetic sampling

[18] - Zero participants analysed due to short half-life of Gemcitabine and sparse pharmacokinetic sampling

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b/2: PK: Cmax of Docetaxel

End point title	Phase 1b/2: PK: Cmax of Docetaxel ^[20]
End point description: Cmax of Docetaxel.	
Analysis Population Description: Phase 1b/2: All participants who received at least one dose of Docetaxel and had evaluable PK data.	
End point type	Secondary
End point timeframe: 5 min, 1, 3, 24, 48 h post-dose on Cycle 1 Day 8	

Notes:

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

Justification: Outcomes were reported by combining phase 1b cohort 2+cohort2expand arms [i.e. Cohort2overall:20mg/kgOlaratumab+Gemcitabine+Docetaxel]; Phase2Olaratumab+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2: Olaratumab+Gemcitabine+Docetaxel]; Phase2Placebo+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Placebo+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2: Placebo+Gemcitabine+Docetaxel]

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2overall: 20mg/kgOlaratumab+Gemcitabine+Docetaxel	Phase2:Olaratumab+Gemcitabine+Docetaxel	Phase2:Placebo+Gemcitabine+Docetaxel
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	30	71	73
Units: Nanograms per milliliter				
geometric mean (geometric coefficient of variation)	903 (± 143)	1110 (± 84)	1030 (± 134)	827 (± 102)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b/2: PK: Area Under the Concentration Versus Time Curve From Time Zero to Infinity (AUC [0-∞]) of Docetaxel

End point title	Phase 1b/2: PK: Area Under the Concentration Versus Time Curve From Time Zero to Infinity (AUC [0-∞]) of Docetaxel ^[21]
End point description:	
Analysis Population Description: Phase 1b/2: All participants who received at least one dose of Docetaxel	

and had evaluable PK data. For phase 2, no participants were analysed due to insufficient sampling.

End point type	Secondary
End point timeframe:	
5 min, 1, 3, 24, 48 h post-dose on Cycle 1 Day 8	

Notes:

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

Justification: Outcomes were reported by combining phase 1b cohort 2+cohort2expand arms [i.e. Cohort2overall:20mg/kgOlaratumab+Gemcitabine+Docetaxel]; Phase2Olaratumab+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2:Olaratumab+Gemcitabine+Docetaxel]; Phase2Placebo+Gemcitabine+Docetaxel (Olaratumab-naïve) +Phase2Placebo+Gemcitabine+Docetaxel(Olaratumab Pretreated) arms [i.e.Phase2:Placebo+Gemcitabine+Docetaxel]

End point values	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2overall- 20mg/kgOlaratumab+Gemcitabine+Docetaxel	Phase2:Olaratumab+Gemcitabine+Docetaxel	Phase2:Placebo+Gemcitabine+Docetaxel
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	18	0 ^[22]	0 ^[23]
Units: nanograms*hours per milliliter				
geometric mean (geometric coefficient of variation)	4440 (± 103)	2990 (± 83)	()	()

Notes:

[22] - No participants were analysed due to insufficient sampling.

[23] - No participants were analysed due to insufficient sampling.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b/2: Population PK: Clearance of Olaratumab

End point title	Phase 1b/2: Population PK: Clearance of Olaratumab
End point description:	
Analysis Population Description: Phase 1b/2: All participants who received at least one dose of Olaratumab and had evaluable PK data. Phase 1b and 2 participants olaratumab PK data had been pooled for this population PK analysis.	
End point type	Secondary
End point timeframe:	
Cycle 1-19: Pre-dose, 5 min, 1, 4, 4.5, 24, 96, 168, 336 h post-dose on days 1, 8	

End point values	Olaratumab + Gemcitabine + Docetaxel			
Subject group type	Subject analysis set			
Number of subjects analysed	178			
Units: Liter Per Hour				
arithmetic mean (confidence interval 95%)	0.0186 (0.0175 to 0.0192)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b/2: Population PK: Volume of Distribution at Steady State (Vss) of Olaratumab

End point title	Phase 1b/2: Population PK: Volume of Distribution at Steady State (Vss) of Olaratumab
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End point description:

The Vss is the sum of central volume of distribution (V1) + peripheral volume of distribution (V2).

Analysis Population Description: Phase 1b/2: All participants who received at least one dose of Olaratumab and had evaluable PK data. Phase 1b and 2 participants olaratumab PK data had been pooled for this population PK analysis.

End point type	Secondary
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End point timeframe:

Cycle 1-19: Pre-dose, 5 min, 1, 4, 4.5, 24, 96, 168, 336 h post-dose on days 1, 8

End point values	Olaratumab + Gemcitabine + Docetaxel			
Subject group type	Subject analysis set			
Number of subjects analysed	178			
Units: Liter				
arithmetic mean (confidence interval 95%)	5.14 (4.68 to 5.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Overall Survival (Olaratumab Pre-Treated)

End point title	Phase 2: Overall Survival (Olaratumab Pre-Treated) ^[24]
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End point description:

OS was defined as the time from the date of randomization to the date of death from any cause. For each participant who is not known to have died as of the data-inclusion cut-off date for a particular analysis, overall survival duration was censored for that analysis at the date of last prior contact.

Analysis Population Description: Phase 2: All randomized participants (including the censored participants). Number of participants censored in "Olaratumab+ Gemcitabine+Docetaxel(Olaratumab Pre-Treated)=20," "Placebo+Gemcitabine+Docetaxel(Olaratumab Pre-Treated)=15."

End point type	Secondary
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End point timeframe:

Baseline to Date of Death Due to Any Cause (Up To 38 Months)

Notes:

[24] - 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: Outcome reporting is only for Phase 2 Olaratumab Pre-Treated participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46 ^[25]	43		
Units: Months				
median (confidence interval 95%)	19.84 (14.19 to 9999)	17.31 (10.81 to 20.30)		

Notes:

[25] - 9999 = N/A, There were not enough events to estimate the upper confidence limit.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab Pretreated)
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.148 ^[26]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.667
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.385
upper limit	1.158

Notes:

[26] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Secondary: Phase 2: Progression Free Survival (PFS)

End point title	Phase 2: Progression Free Survival (PFS) ^[27]
End point description:	<p>PFS was 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. Progressive disease (PD) was defined as at least a 20% increase in the sum of the diameters of target lesions, with reference being the smallest sum on study and an absolute increase of at least 5 mm, or unequivocal progression of non-target lesions, or 1 or more new lesions. Participants who have neither progressed nor died 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.</p> <p>Analysis Population Description: Phase 2: All randomized participants (including censored). Number of participants censored in Olaratumab+Gemcitabine+Docetaxel (Olaratumab-naive=20, Olaratumab pretreated=12), Placebo+Gemcitabine+Docetaxel(Olaratumab-naive=21, Olaratumab pretreated=16).</p>
End point type	Secondary

End point timeframe:

Baseline to Objective Disease Progression or Death from Any Cause (Up To 38 Months)

Notes:

[27] - 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: Outcome reporting is only for Phase 2 participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	46	86	43
Units: Months				
median (confidence interval 95%)	7.62 (5.13 to 8.54)	5.45 (2.76 to 8.71)	4.37 (2.86 to 6.87)	4.17 (2.20 to 6.90)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.055 ^[28]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.692
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.476
upper limit	1.007

Notes:

[28] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 2
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.482 ^[29]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.828

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.398

Notes:

[29] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Secondary: Phase 2: Percentage of Participants With a Complete or Partial Response (Objective Response Rate [ORR])

End point title	Phase 2: Percentage of Participants With a Complete or Partial Response (Objective Response Rate [ORR]) ^[30]
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End point description:

ORR is the best overall tumor response of complete response (CR) or partial response (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.

Analysis Population Description: Phase 2: All randomized participants.

End point type	Secondary
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End point timeframe:

Baseline to Objective Disease Progression or Start of New Anti-Cancer Therapy (Up To 38 Months)

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: Outcome reporting is only for Phase 2 participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	46	86	43
Units: Percentage of participants				
number (confidence interval 95%)	32.1 (22.2 to 43.4)	30.4 (17.7 to 45.8)	23.3 (14.8 to 33.6)	14 (5.3 to 27.9)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1891 ^[31]
Method	Exact Mantel-Haenszel test
Parameter estimate	Odds ratio (OR)
Point estimate	1.589
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.794
upper limit	3.179

Notes:

[31] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs 1).

Statistical analysis title	Statistical analysis 2
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0642 ^[32]
Method	Exact Mantel-Haenszel test
Parameter estimate	Odds ratio (OR)
Point estimate	2.668
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.923
upper limit	7.71

Notes:

[32] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs 1).

Secondary: Phase 2: Disease Control Rate (DCR): Percentage of Participants With a Best Overall Response of Complete Response (CR), Partial Response (PR), and Stable Disease (SD)

End point title	Phase 2: Disease Control Rate (DCR): Percentage of Participants With a Best Overall Response of Complete Response (CR), Partial Response (PR), and Stable Disease (SD) ^[33]
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End point description:

DCR is the percentage of participants with a best overall response of CR, PR or SD as defined by RECIST v1.1. CR is defined as the disappearance of all target and non-target lesions and no appearance of new lesions. PR is defined as at least a 30% decrease in the sum of the longest diameter (LD) of target lesions (taking as reference the baseline sum LD), no progression of non-target lesions, and no appearance of new lesions. SD is neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD) for target lesions, no progression of non-target lesions, and no appearance of new lesions. PD is defined as at least a 20% increase in the sum of the diameters of target lesions, with reference being the smallest sum on study and an absolute increase of at least 5 mm, or unequivocal progression of non-target lesions, or 1 or more new lesions.

Analysis Population Description: Phase 2: All randomized participants

End point type	Secondary
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End point timeframe:

Baseline to Measured Progressive Disease or Start of New Anti-Cancer Therapy (Up To 38 Months)

Notes:

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

Justification: Outcome reporting is only for Phase 2 participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	46	86	43
Units: Percentage of participants				
number (confidence interval 95%)	74.1 (63.1 to 83.2)	67.4 (52.0 to 80.5)	72.1 (61.4 to 81.2)	62.8 (46.7 to 77.0)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7724 [34]
Method	Exact Mantel-Haenszel test
Parameter estimate	Odds ratio (OR)
Point estimate	1.106
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.558
upper limit	2.194

Notes:

[34] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 2
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6508 [35]
Method	Exact Mantel-Haenszel test
Parameter estimate	Odds ratio (OR)
Point estimate	1.222

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.513
upper limit	2.911

Notes:

[35] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs 1).

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" ^[36]
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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) to 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 (\geq) 2 points from baseline or an analgesic drug class increase of ≥ 1 level. If the patient has not worsened by either of these criteria, TWP was censored for analysis on the last date the mBPI-sf was administered.

Analysis Population Description: Phase 2: All randomized participants who had baseline and at least one post-baseline assessment (including the censored participants). Number of participants censored in Olaratumab+Gemcitabine+Docetaxel (Olaratumab-naive=30, Olaratumab pretreated=17), Placebo+Gemcitabine+Docetaxel(Olaratumab-naive=23, Olaratumab pretreated=8).

End point type	Secondary
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End point timeframe:

Baseline to Follow-up (Up To 24 Months)

Notes:

[36] - 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: Outcome reporting is only for Phase 2 participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	41	71	34
Units: Months				
median (confidence interval 95%)	3.61 (2.66 to 8.57)	3.15 (1.41 to 7.62)	2.27 (1.41 to 6.54)	2.20 (0.76 to 3.02)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)

Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 ^[37]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.661
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.419
upper limit	1.041

Notes:

[37] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 2
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.225 ^[38]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.703
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.395
upper limit	1.253

Notes:

[38] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

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. ^[39]
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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 items addressing either physical,role,emotional,cognitive,or social functioning), symptom scales (13 items addressing either fatigue,nausea/vomiting,pain,dyspnoea,insomnia,appetite loss,constipation,diarrhoea,or financial impact). Time to first worsening of Symptom Burden was 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.

Analysis Population Description: Phase 2: All randomized participants who had baseline and at least one post-baseline assessment.

9999=N/A, There were not enough events to estimate the median/upper confidence limit, as applicable.

End point type	Secondary
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End point timeframe:

Baseline to Follow-up (Up to 33 months)

Notes:

[39] - 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: Outcome reporting is only for Phase 2 participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75 ^[40]	45 ^[41]	78 ^[42]	41 ^[43]
Units: Months				
median (confidence interval 95%)				
Fatigue	0.95 (0.76 to 1.12)	0.85 (0.72 to 1.41)	0.95 (0.76 to 1.45)	0.76 (0.72 to 1.84)
Nausea and vomiting	3.78 (2.14 to 9999)	3.98 (1.41 to 9999)	2.46 (0.99 to 13.34)	13.17 (1.64 to 9999)
Pain	4.67 (2.33 to 9.53)	2.43 (1.41 to 8.77)	0.99 (0.79 to 2.76)	3.06 (0.76 to 5.55)
Dyspnoea	2.14 (1.51 to 3.06)	2.33 (1.45 to 14.09)	2.14 (1.48 to 2.86)	2.79 (1.45 to 8.05)
Insomnia	5.32 (2.33 to 7.72)	1.91 (1.41 to 6.47)	4.24 (1.48 to 16.82)	5.09 (1.45 to 9999)
Appetite loss	1.12 (0.82 to 2.14)	1.41 (0.85 to 3.52)	2.56 (1.64 to 3.98)	1.97 (1.38 to 4.04)
Constipation	3.25 (2.14 to 5.98)	4.63 (1.91 to 12.91)	2.86 (1.48 to 9999)	3.81 (1.97 to 9999)
Diarrhoea	1.41 (0.99 to 3.68)	3.55 (1.41 to 6.05)	1.81 (1.41 to 4.24)	3.52 (1.97 to 9999)
Financial difficulties	9999 (5.32 to 9999)	7.29 (2.33 to 7.85)	7.66 (3.29 to 9999)	9999 (3.94 to 9999)

Notes:

[40] - Nausea/vomiting,Dyspnoea=74, Pain,Constipation,Appetite loss=73, Insomnia=68,Financial difficulty=67

[41] - Fatigue,Nausea&vomiting,Pain,Constipation,Diarrhoea=44, Financial,Dyspnoea=43,Insomnia=41

[42] - Constipation,Fatigue,Pain=77,Insomnia=74,Appetite loss=76,Diarrhoea=80,Financial difficulty=71

[43] - Fatigue,Dyspnoea,=39,Pain,Financial difficulty=35,Insomnia=38,Appetite loss=37, Constipation=40

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Fatigue	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)

Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[44]
P-value	= 0.332 ^[45]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.213
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.834
upper limit	1.764

Notes:

[44] - Fatigue

[45] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Nausea and vomiting	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[46]
P-value	= 0.389 ^[47]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.813
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.514
upper limit	1.287

Notes:

[46] - Nausea and vomiting

[47] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Pain	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[48]
P-value	= 0.02 ^[49]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.598

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.386
upper limit	0.926

Notes:

[48] - Pain

[49] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Dyspnoea	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[50]
P-value	= 0.821 ^[51]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.947
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.622
upper limit	1.442

Notes:

[50] - Dyspnoea

[51] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 5
Statistical analysis description:	
Insomnia	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[52]
P-value	= 0.812 ^[53]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.931
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.574
upper limit	1.509

Notes:

[52] - Insomnia

[53] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 6
Statistical analysis description:	
Appetite loss	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[54]
P-value	= 0.162 ^[55]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.355
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.893
upper limit	2.055

Notes:

[54] - Appetite loss

[55] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 7
Statistical analysis description:	
Constipation	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[56]
P-value	= 0.619 ^[57]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.881
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	1.413

Notes:

[56] - Constipation

[57] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 8
Statistical analysis description:	
Diarrhoea	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)

	naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[58]
P-value	= 0.597 ^[59]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.134
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.746
upper limit	1.724

Notes:

[58] - Diarrhoea

[59] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 9
Statistical analysis description:	
Financial difficulties	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority ^[60]
P-value	= 0.38 ^[61]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.766
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.425
upper limit	1.381

Notes:

[60] - Financial difficulties

[61] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Fatigue	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[62]
P-value	= 0.877 ^[63]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.046

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.635
upper limit	1.723

Notes:

[62] - Fatigue

[63] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 11
Statistical analysis description:	
Nausea and vomiting	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[64]
P-value	= 0.791 ^[65]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.102
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.568
upper limit	2.139

Notes:

[64] - Nausea and vomiting

[65] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Pain	
Comparison groups	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated) v Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[66]
P-value	= 0.487 ^[67]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.454
upper limit	1.443

Notes:

[66] - Pain

[67] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 13
Statistical analysis description:	
Dyspnoea	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[68]
P-value	= 0.976 ^[69]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.014
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.556
upper limit	1.85

Notes:

[68] - Dyspnoea

[69] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 14
Statistical analysis description:	
Insomnia	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[70]
P-value	= 0.111 ^[71]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.694
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.882
upper limit	3.25

Notes:

[70] - Insomnia

[71] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 15
Statistical analysis description:	
Appetite loss	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel

	(Olaratumab pretreated)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[72]
P-value	= 0.76 ^[73]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.108
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.979

Notes:

[72] - Appetite loss

[73] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 16
Statistical analysis description:	
Constipation	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[74]
P-value	= 0.747 ^[75]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.119
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.586
upper limit	2.135

Notes:

[74] - Constipation

[75] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs1).

Statistical analysis title	Statistical analysis 17
Statistical analysis description:	
Diarrhoea	
Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[76]
P-value	= 0.33 ^[77]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.367

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.726
upper limit	2.576

Notes:

[76] - Diarrhoea

[77] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs 1).

Statistical analysis title	Statistical analysis 18
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Statistical analysis description:

Financial difficulties

Comparison groups	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated) v Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority ^[78]
P-value	= 0.411 ^[79]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.373

Confidence interval

level	95 %
sides	2-sided
lower limit	0.636
upper limit	2.965

Notes:

[78] - Financial difficulties

[79] - Stratified by number of prior systemic therapies for locally advanced or metastatic disease (0 vs ≥ 1), histological tumor type (leiomyosarcoma vs non-leiomyosarcoma), and ECOG PS (0 vs 1).

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) ^[80]
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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.

Analysis Population Description: Phase 2: All randomized participants who completed EQ-5D-5L.

End point type	Secondary
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End point timeframe:

Cycle 1 (Day 1), Follow-up (Up to 38 Months)

Notes:

[80] - 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: Outcome reporting is only for Phase 2 participants.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71 ^[81]	42 ^[82]	75 ^[83]	35 ^[84]
Units: score on a scale				
arithmetic mean (standard deviation)				
EQ-5D-5L - Index Value [Cycle 1 (Day 1)]	0.80 (± 0.17)	0.83 (± 0.15)	0.81 (± 0.17)	0.83 (± 0.22)
EQ-5D-5L - VAS Score [Cycle 1 (Day 1)]	73.5 (± 18.9)	76.2 (± 19.6)	72.7 (± 18.1)	70.3 (± 23.8)
EQ-5D-5L - Index Value [Follow-up (Up to 38 Months)	0.74 (± 0.21)	0.80 (± 0.20)	0.71 (± 0.26)	0.76 (± 0.24)
EQ-5D-5L - VAS Score [Follow-up (Up to 38 Months)]	68.7 (± 16.5)	74.8 (± 21.8)	63.0 (± 21.6)	70.8 (± 24.2)

Notes:

[81] - EQ-5D-5L- Index Value, VAS Score Follow-up (Up to 38 Months) = 42 Participants

[82] - EQ-5D-5L- Index Value Cycle 1 (Day 1) = 39; Index Value, VAS Score Follow-up (Up to 38 Months) = 26

[83] - EQ-5D-5L- Index Value Cycle 1 (Day 1) = 74; Index Value, VAS Score Follow-up (Up to 38 Months) = 50

[84] - EQ-5D-5L- Index Value, VAS Score Follow-up (Up to 38 Months) = 25

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 ^[85]
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End point description:

Phase 2: Analysis Population Description: All randomized participants who received at least one dose of Olaratumab and had evaluable immunogenicity data.

End point type	Secondary
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End point timeframe:

Baseline through Follow-Up (Up to 38 Months)

Notes:

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

Justification: No inferential statistics were planned for this endpoint.

End point values	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	43		
Units: Participants	0	0		

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 38 Months)

Adverse event reporting additional description:

Phase 1b/2: All participants 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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.0
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Reporting groups

Reporting group title	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel
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Reporting group description:

Participants received intravenous infusions of olaratumab 15 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m²) on days 1, 8 plus docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel
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Reporting group description:

Participants received intravenous infusions of olaratumab 20 mg/kg on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase1b:Cohort2Expand:20mg/kgOlaratumab+Gemcitabine+D ocetaxel
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Reporting group description:

Following a protocol amendment, additional participants were enrolled into this group to confirm the safety of the 20 mg/kg dose level prior to opening the Phase 2. Participants received intravenous infusions of olaratumab 20 milligrams per kilogram (mg/kg) on days 1, 8 plus gemcitabine 900 milligrams per meter square (mg/m²) on days 1, 8 plus docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab- naive)
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Reporting group description:

This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)
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Reporting group description:

This cohort included participants who received commercially available olaratumab prior to enrollment. Participants received intravenous infusions of olaratumab loading dose 20 mg/kg on days 1, 8 of cycle 1 followed by 15 mg/kg on days 1, 8 of all subsequent cycles in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
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Reporting group description:

This cohort included participants who never received olaratumab prior to enrollment. Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Reporting group title	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab
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Reporting group description:

This cohort included participants who received commercially available olaratumab prior to enrollment. Participants received intravenous infusions of placebo on days 1, 8 in combination with gemcitabine 900 mg/m² on days 1, 8 and docetaxel 75 mg/m² on day 8 of a 21-day cycle until disease progression, unacceptable toxicity, death, or other discontinuation criteria were met.

Serious adverse events	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2Exp and:20mg/kgOlaratumab+Gemcitabine+Docetaxel
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 21 (28.57%)	9 / 18 (50.00%)	9 / 15 (60.00%)
number of deaths (all causes)	1	2	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
capillary leak syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (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
peripheral artery stenosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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			
chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza like illness			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mucosal inflammation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

sudden death			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anaphylactic shock			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (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
epistaxis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoxia			

alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
interstitial lung disease				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pneumonitis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pneumothorax				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pulmonary embolism				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pulmonary haemorrhage				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pulmonary oedema				
alternative dictionary used: MedDRA 21.0				

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
international normalised ratio increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutrophil count decreased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
troponin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
white blood cell count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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			
arterial bypass occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hip fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infusion related reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (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
skull fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
pericardial effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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			
dizziness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial paralysis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nervous system disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyneuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal cord compression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (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
bandaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
febrile neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemolytic uraemic syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypochromic anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (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
neutrophilia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
normocytic anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombocytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombotic microangiopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
hypoacusis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (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
constipation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

oesophageal ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stomatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
hepatic failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
jaundice cholestatic			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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			
eczema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
petechiae			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
back pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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			
anorectal infection			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis infective			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bacteraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (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
bronchitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
campylobacter infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	2 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

clostridium difficile colitis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cystitis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 infection alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (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
diverticulitis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 infection alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower respiratory tract infection alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenic sepsis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
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 21.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
pneumonia bacterial alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (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
pneumonia viral alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal abscess alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

respiratory tract infection alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
sepsis alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (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	
septic shock alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
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 infection alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
staphylococcal bacteraemia alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
urinary tract infection alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
viral infection alternative dictionary used: MedDRA 21.0				

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab+Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Total subjects affected by serious adverse events			
subjects affected / exposed	44 / 81 (54.32%)	21 / 45 (46.67%)	38 / 86 (44.19%)
number of deaths (all causes)	0	1	2
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
capillary leak syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
deep vein thrombosis			

alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	2 / 45 (4.44%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 1	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
hypotension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
peripheral artery stenosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
fatigue			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza like illness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mucosal inflammation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	2 / 45 (4.44%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	1 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

peripheral swelling alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
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 21.0			
subjects affected / exposed	7 / 81 (8.64%)	2 / 45 (4.44%)	7 / 86 (8.14%)
occurrences causally related to treatment / all	7 / 10	1 / 2	4 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sudden death alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders anaphylactic reaction alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
anaphylactic shock alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			

alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	2 / 45 (4.44%)	4 / 86 (4.65%)
occurrences causally related to treatment / all	2 / 4	1 / 2	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epistaxis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
interstitial lung disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
pneumonitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	1 / 45 (2.22%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	1 / 1	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary haemorrhage alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
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 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
respiratory failure alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
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 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
international normalised ratio increased alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutrophil count decreased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
platelet count decreased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	2 / 2	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
troponin increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
white blood cell count decreased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
arterial bypass occlusion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
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 21.0			

subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
femur fracture alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
hip fracture alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
infusion related reaction alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
skull fracture alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac disorders atrial fibrillation alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
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			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
pericardial effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epilepsy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial paralysis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nervous system disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
polyneuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

spinal cord compression alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	2 / 45 (4.44%)	4 / 86 (4.65%)
occurrences causally related to treatment / all	4 / 7	2 / 2	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bandaemia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
febrile neutropenia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 81 (7.41%)	1 / 45 (2.22%)	3 / 86 (3.49%)
occurrences causally related to treatment / all	6 / 6	1 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemolytic uraemic syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypochromic anaemia alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	2 / 45 (4.44%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	1 / 1	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutrophilia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
normocytic anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
pancytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombocytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	3 / 45 (6.67%)	3 / 86 (3.49%)
occurrences causally related to treatment / all	3 / 3	5 / 5	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombotic microangiopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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

Ear and labyrinth disorders hypoacusis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 81 (0.00%) 0 / 0 0 / 0	 0 / 45 (0.00%) 0 / 0 0 / 0	 1 / 86 (1.16%) 0 / 1 0 / 0
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 81 (1.23%) 1 / 1 0 / 0	 0 / 45 (0.00%) 0 / 0 0 / 0	 0 / 86 (0.00%) 0 / 0 0 / 0
constipation alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 81 (0.00%) 0 / 0 0 / 0	 1 / 45 (2.22%) 1 / 1 0 / 0	 0 / 86 (0.00%) 0 / 0 0 / 0
diarrhoea alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 2 / 81 (2.47%) 2 / 2 0 / 0	 1 / 45 (2.22%) 0 / 1 0 / 0	 1 / 86 (1.16%) 1 / 1 0 / 0
enterocolitis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 81 (1.23%) 1 / 1 0 / 0	 0 / 45 (0.00%) 0 / 0 0 / 0	 0 / 86 (0.00%) 0 / 0 0 / 0
gastritis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 81 (0.00%) 0 / 0 0 / 0	 0 / 45 (0.00%) 0 / 0 0 / 0	 1 / 86 (1.16%) 1 / 1 0 / 0
haemorrhoidal haemorrhage alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stomatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
hepatic failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
jaundice cholestatic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
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			
eczema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
petechiae			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary retention			

alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
back pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
myositis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
anorectal infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
appendicitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
arthritis infective			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bacteraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
campylobacter infection			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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
cellulitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastrointestinal infection				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (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	
influenza				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	1 / 86 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
lower respiratory tract infection				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	1 / 86 (1.16%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
neutropenic sepsis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pneumonia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	5 / 81 (6.17%)	3 / 45 (6.67%)	6 / 86 (6.98%)	
occurrences causally related to treatment / all	4 / 5	2 / 3	2 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pneumonia bacterial				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
pneumonia viral				
alternative dictionary used: MedDRA 21.0				

subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
septic shock			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
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 infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (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
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	3 / 4	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)		
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 43 (53.49%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Vascular disorders				
capillary leak syndrome				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
deep vein thrombosis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
embolism				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haematoma				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemorrhage				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypotension				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral artery stenosis				
alternative dictionary used: MedDRA 21.0				

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fatigue			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
influenza like illness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
mucosal inflammation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
oedema			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
peripheral swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
pyrexia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 43 (13.95%)		
occurrences causally related to treatment / all	2 / 6		
deaths causally related to treatment / all	0 / 0		
sudden death			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
anaphylactic shock			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
dyspnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
epistaxis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
interstitial lung disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pneumonitis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	4 / 43 (9.30%)		
occurrences causally related to treatment / all	4 / 4		
deaths causally related to treatment / all	0 / 0		
pneumothorax			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
pulmonary embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
pulmonary haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pulmonary oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
respiratory failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	1 / 1		
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
international normalised ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
platelet count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
troponin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
white blood cell count decreased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
arterial bypass occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fall			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
femoral neck fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
femur fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hip fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
infusion related reaction			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
skull fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
atrial tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cardiac failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
myocardial infarction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pericardial effusion			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
epilepsy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
facial paralysis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
nervous system disorder			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
polyneuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
seizure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
spinal cord compression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
syncope			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bandaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
febrile neutropenia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
haemolytic uraemic syndrome				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypochromic anaemia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
neutropenia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
neutrophilia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
normocytic anaemia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

<p>pancytopenia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 43 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>thrombocytopenia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>2 / 43 (4.65%)</p> <p>2 / 2</p> <p>0 / 0</p>		
<p>thrombotic microangiopathy</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 43 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>Ear and labyrinth disorders</p> <p>hypoacusis</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 43 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>Gastrointestinal disorders</p> <p>abdominal pain</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 43 (2.33%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>constipation</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 43 (2.33%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>diarrhoea</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
enterocolitis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastritis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemorrhoidal haemorrhage				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
nausea				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oesophageal ulcer				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
rectal haemorrhage				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

small intestinal obstruction alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0		
stomatitis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0		
vomiting alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0		
Hepatobiliary disorders hepatic failure alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0		
jaundice cholestatic alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 43 (2.33%) 0 / 1 0 / 0		
Skin and subcutaneous tissue disorders eczema alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0		
petechiae alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
renal failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
urinary retention			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
arthritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
back pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
myositis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
anorectal infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
appendicitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
arthritis infective			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bacteraemia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bronchitis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
campylobacter infection				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
clostridium difficile colitis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cystitis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

device related infection				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diverticulitis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
erysipelas				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastrointestinal infection				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
influenza				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lower respiratory tract infection				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
neutropenic sepsis				
alternative dictionary used: MedDRA 21.0				

subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	5 / 43 (11.63%)			
occurrences causally related to treatment / all	3 / 5			
deaths causally related to treatment / all	0 / 0			
pneumonia bacterial				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia viral				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rectal abscess				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
respiratory tract infection				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	2 / 43 (4.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

septic shock alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 43 (2.33%) 1 / 1 0 / 0			
skin infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 43 (2.33%) 0 / 1 0 / 0			
staphylococcal bacteraemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0			
urinary tract infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0			
viral infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 43 (0.00%) 0 / 0 0 / 0			
Metabolism and nutrition disorders dehydration alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all hypokalaemia alternative dictionary used: MedDRA 21.0	0 / 43 (0.00%) 0 / 0 0 / 0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Phase1b:Cohort1: 15mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2: 20mg/kg Olaratumab+Gemcitabine+Docetaxel	Phase1b:Cohort2Exp and:20mg/kgOlaratumab+Gemcitabine+Docetaxel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)	18 / 18 (100.00%)	15 / 15 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) tumour pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 4	0 / 18 (0.00%) 0	0 / 15 (0.00%) 0
Vascular disorders embolism alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
embolism venous alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
flushing alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
hot flush alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	0 / 18 (0.00%) 0	0 / 15 (0.00%) 0
hypertension alternative dictionary used: MedDRA 21.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 21 (14.29%)</p> <p>3</p>	<p>0 / 18 (0.00%)</p> <p>0</p>	<p>2 / 15 (13.33%)</p> <p>2</p>
<p>hypotension</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 21 (9.52%)</p> <p>2</p>	<p>0 / 18 (0.00%)</p> <p>0</p>	<p>2 / 15 (13.33%)</p> <p>2</p>
<p>peripheral venous disease</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>1 / 18 (5.56%)</p> <p>1</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>phlebitis</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>1 / 18 (5.56%)</p> <p>1</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>Surgical and medical procedures</p> <p>orchidectomy</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed^[1]</p> <p>occurrences (all)</p>	<p>0 / 10 (0.00%)</p> <p>0</p>	<p>0 / 10 (0.00%)</p> <p>0</p>	<p>1 / 8 (12.50%)</p> <p>1</p>
<p>General disorders and administration site conditions</p> <p>asthenia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>4 / 21 (19.05%)</p> <p>21</p>	<p>2 / 18 (11.11%)</p> <p>8</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>catheter site pain</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>0 / 18 (0.00%)</p> <p>0</p>	<p>1 / 15 (6.67%)</p> <p>1</p>
<p>chills</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 21 (4.76%)</p> <p>1</p>	<p>2 / 18 (11.11%)</p> <p>3</p>	<p>1 / 15 (6.67%)</p> <p>1</p>
<p>device related thrombosis</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
face oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	13 / 21 (61.90%)	14 / 18 (77.78%)	12 / 15 (80.00%)
occurrences (all)	32	35	21
influenza like illness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	2 / 18 (11.11%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
infusion site extravasation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
localised oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
malaise			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 21 (9.52%)	1 / 18 (5.56%)	1 / 15 (6.67%)
occurrences (all)	2	1	1
non-pitting oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

oedema peripheral alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	8 / 21 (38.10%) 13	5 / 18 (27.78%) 9	5 / 15 (33.33%) 8
pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	2 / 18 (11.11%) 2	0 / 15 (0.00%) 0
peripheral swelling alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
pyrexia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	6 / 21 (28.57%) 8	8 / 18 (44.44%) 11	2 / 15 (13.33%) 2
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 3	6 / 18 (33.33%) 9	1 / 15 (6.67%) 3
dyspnoea alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 4	7 / 18 (38.89%) 11	5 / 15 (33.33%) 9
dyspnoea exertional alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	0 / 15 (0.00%) 0
epistaxis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 4	1 / 18 (5.56%) 1	2 / 15 (13.33%) 5
haemoptysis alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
hiccups			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	3 / 18 (16.67%)	1 / 15 (6.67%)
occurrences (all)	0	3	1
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
laryngeal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
nasal congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 21 (14.29%)	2 / 18 (11.11%)	1 / 15 (6.67%)
occurrences (all)	3	3	2
nasal dryness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
pleural effusion			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
pneumonitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
productive cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
pulmonary embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
upper-airway cough syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	3 / 18 (16.67%)	2 / 15 (13.33%)
occurrences (all)	0	5	2
depression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
insomnia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
nightmare			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 21 (23.81%)	6 / 18 (33.33%)	2 / 15 (13.33%)
occurrences (all)	7	13	2
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 21 (19.05%)	4 / 18 (22.22%)	2 / 15 (13.33%)
occurrences (all)	4	7	2
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 21 (19.05%)	3 / 18 (16.67%)	2 / 15 (13.33%)
occurrences (all)	4	6	2
blood bilirubin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	3 / 18 (16.67%)	0 / 15 (0.00%)
occurrences (all)	0	4	0
blood creatinine increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 21 (19.05%)	3 / 18 (16.67%)	0 / 15 (0.00%)
occurrences (all)	5	5	0
haemoglobin decreased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
international normalised ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	3 / 18 (16.67%)	2 / 15 (13.33%)
occurrences (all)	0	3	2
lymphocyte count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	4 / 18 (22.22%)	0 / 15 (0.00%)
occurrences (all)	3	15	0
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	5 / 18 (27.78%)	0 / 15 (0.00%)
occurrences (all)	3	7	0
platelet count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 21 (9.52%)	7 / 18 (38.89%)	2 / 15 (13.33%)
occurrences (all)	2	15	2
transaminases increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	3
weight decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	4 / 18 (22.22%)	0 / 15 (0.00%)
occurrences (all)	0	6	0
weight increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
white blood cell count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 21 (14.29%)	4 / 18 (22.22%)	0 / 15 (0.00%)
occurrences (all)	3	11	0

Injury, poisoning and procedural complications fall alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
infusion related reaction alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 3	1 / 18 (5.56%) 1	2 / 15 (13.33%) 2
meniscus injury alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
wound complication alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
Cardiac disorders atrial fibrillation alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
sinus tachycardia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
tachycardia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
Nervous system disorders dizziness alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	2 / 18 (11.11%) 2	2 / 15 (13.33%) 4

dysgeusia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 21 (14.29%)	7 / 18 (38.89%)	0 / 15 (0.00%)
occurrences (all)	7	7	0
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 21 (23.81%)	5 / 18 (27.78%)	1 / 15 (6.67%)
occurrences (all)	6	5	1
memory impairment			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
neuropathy peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
paraesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
peripheral motor neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	3 / 18 (16.67%)	1 / 15 (6.67%)
occurrences (all)	0	4	1
sciatica			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
syncope			
alternative dictionary used: MedDRA 21.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>0 / 18 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>taste disorder</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>0 / 18 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>13 / 21 (61.90%)</p> <p>42</p>	<p>12 / 18 (66.67%)</p> <p>54</p>	<p>9 / 15 (60.00%)</p> <p>24</p>
<p>leukopenia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>0 / 18 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>neutropenia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 21 (14.29%)</p> <p>4</p>	<p>3 / 18 (16.67%)</p> <p>4</p>	<p>2 / 15 (13.33%)</p> <p>5</p>
<p>neutrophilia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>0 / 18 (0.00%)</p> <p>0</p>	<p>1 / 15 (6.67%)</p> <p>1</p>
<p>thrombocytopenia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 21 (9.52%)</p> <p>8</p>	<p>3 / 18 (16.67%)</p> <p>3</p>	<p>4 / 15 (26.67%)</p> <p>12</p>
<p>Ear and labyrinth disorders</p> <p>ear pain</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 21 (0.00%)</p> <p>0</p>	<p>1 / 18 (5.56%)</p> <p>1</p>	<p>1 / 15 (6.67%)</p> <p>1</p>
<p>Eye disorders</p> <p>dry eye</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
lacrimation increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
photopsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
vision blurred			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	4	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 21 (14.29%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
anorectal discomfort			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
aphthous ulcer			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
constipation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 21 (28.57%)	3 / 18 (16.67%)	4 / 15 (26.67%)
occurrences (all)	8	7	6
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 21 (33.33%)	8 / 18 (44.44%)	5 / 15 (33.33%)
occurrences (all)	22	14	8
dry mouth			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	3 / 18 (16.67%)	1 / 15 (6.67%)
occurrences (all)	0	3	2
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	2
haemorrhoids			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
intestinal fistula			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 21 (23.81%)	9 / 18 (50.00%)	3 / 15 (20.00%)
occurrences (all)	8	15	4

oral pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	2 / 18 (11.11%) 3	0 / 15 (0.00%) 0
proctalgia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
salivary hypersecretion alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
stomatitis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 8	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
toothache alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
vomiting alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 5	2 / 18 (11.11%) 2	1 / 15 (6.67%) 1
Skin and subcutaneous tissue disorders			
alopecia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	8 / 21 (38.10%) 8	5 / 18 (27.78%) 10	1 / 15 (6.67%) 1
dermatitis acneiform alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
dry skin alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
eczema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
erythema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
nail discolouration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
nail dystrophy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 21 (14.29%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	3	1	0
onychomadesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
palmar-plantar erythrodysaesthesia syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
pruritus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
rash			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1

rash maculo-papular alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	2 / 18 (11.11%) 2	2 / 15 (13.33%) 2
rash pruritic alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
skin hyperpigmentation alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	0 / 15 (0.00%) 0
Renal and urinary disorders			
chromaturia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
haematuria alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	0 / 15 (0.00%) 0
micturition urgency alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
proteinuria alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 2	0 / 18 (0.00%) 0	0 / 15 (0.00%) 0
Endocrine disorders			
adrenal insufficiency alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
hypothyroidism			

alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	2 / 18 (11.11%) 2	0 / 15 (0.00%) 0
Musculoskeletal and connective tissue disorders			
arthralgia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 3	3 / 18 (16.67%) 4	2 / 15 (13.33%) 3
back pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 6	5 / 18 (27.78%) 7	6 / 15 (40.00%) 7
bone pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 3	3 / 18 (16.67%) 3	0 / 15 (0.00%) 0
coccydynia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
muscle spasms alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	0 / 15 (0.00%) 0
muscular weakness alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	2 / 18 (11.11%) 2	1 / 15 (6.67%) 1
musculoskeletal chest pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	2 / 18 (11.11%) 5	0 / 15 (0.00%) 0
musculoskeletal pain alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 21 (9.52%)	1 / 18 (5.56%)	1 / 15 (6.67%)
occurrences (all)	2	1	1
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 21 (33.33%)	6 / 18 (33.33%)	4 / 15 (26.67%)
occurrences (all)	9	6	4
pain in extremity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	1 / 15 (6.67%)
occurrences (all)	0	4	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
cellulitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
folliculitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
oral candidiasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
oral herpes			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
paronychia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
pneumonia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
rash pustular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
skin infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 21 (9.52%)	2 / 18 (11.11%)	3 / 15 (20.00%)
occurrences (all)	2	2	3
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	2 / 18 (11.11%)	0 / 15 (0.00%)
occurrences (all)	1	2	0

vaginal infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[2] occurrences (all)	0 / 11 (0.00%) 0	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	5 / 21 (23.81%) 6	6 / 18 (33.33%) 8	0 / 15 (0.00%) 0
dehydration alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
failure to thrive alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 18 (0.00%) 0	1 / 15 (6.67%) 1
hypercalcaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 2	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
hyperglycaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 4	4 / 18 (22.22%) 5	0 / 15 (0.00%) 0
hyperkalaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	1 / 18 (5.56%) 2	0 / 15 (0.00%) 0
hypernatraemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 18 (5.56%) 1	0 / 15 (0.00%) 0
hyperuricaemia alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 21 (9.52%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
hypoalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	3 / 18 (16.67%)	0 / 15 (0.00%)
occurrences (all)	1	4	0
hypocalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 21 (0.00%)	4 / 18 (22.22%)	0 / 15 (0.00%)
occurrences (all)	0	4	0
hypokalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 21 (9.52%)	5 / 18 (27.78%)	1 / 15 (6.67%)
occurrences (all)	2	10	1
hypomagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
hyponatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 21 (4.76%)	3 / 18 (16.67%)	0 / 15 (0.00%)
occurrences (all)	8	4	0
hypophosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 21 (9.52%)	1 / 18 (5.56%)	0 / 15 (0.00%)
occurrences (all)	2	1	0

Non-serious adverse events	Phase2:Olaratumab +Gemcitabine+Docetaxel(Olaratumab-naive)	Phase2:Olaratumab +Gemcitabine+Docetaxel(Olaratumab Pretreated)	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab-naive)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	78 / 81 (96.30%)	45 / 45 (100.00%)	81 / 86 (94.19%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 1	1 / 45 (2.22%) 1	2 / 86 (2.33%) 4
Vascular disorders			
embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	2 / 45 (4.44%)	6 / 86 (6.98%)
occurrences (all)	1	2	6
embolism venous			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
flushing			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 81 (11.11%)	2 / 45 (4.44%)	4 / 86 (4.65%)
occurrences (all)	12	2	7
hot flush			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	1 / 45 (2.22%)	5 / 86 (5.81%)
occurrences (all)	5	1	9
hypertension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 81 (6.17%)	6 / 45 (13.33%)	7 / 86 (8.14%)
occurrences (all)	20	6	23
hypotension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	8 / 45 (17.78%)	5 / 86 (5.81%)
occurrences (all)	4	8	5
peripheral venous disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
phlebitis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 1	0 / 45 (0.00%) 0	1 / 86 (1.16%) 1
Surgical and medical procedures orchidectomy alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[1] occurrences (all)	0 / 33 (0.00%) 0	0 / 17 (0.00%) 0	0 / 28 (0.00%) 0
General disorders and administration site conditions asthenia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	12 / 81 (14.81%) 59	1 / 45 (2.22%) 1	14 / 86 (16.28%) 58
catheter site pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 1	0 / 45 (0.00%) 0	0 / 86 (0.00%) 0
chills alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	8 / 81 (9.88%) 13	5 / 45 (11.11%) 5	4 / 86 (4.65%) 5
device related thrombosis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 1	0 / 45 (0.00%) 0	0 / 86 (0.00%) 0
face oedema alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	5 / 81 (6.17%) 8	2 / 45 (4.44%) 2	0 / 86 (0.00%) 0
fatigue alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	49 / 81 (60.49%) 126	34 / 45 (75.56%) 76	45 / 86 (52.33%) 110
influenza like illness alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 81 (6.17%)	3 / 45 (6.67%)	3 / 86 (3.49%)
occurrences (all)	5	3	6
infusion site extravasation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	2	0	0
localised oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	3 / 45 (6.67%)	0 / 86 (0.00%)
occurrences (all)	1	3	0
malaise			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	2 / 86 (2.33%)
occurrences (all)	3	1	2
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 81 (8.64%)	3 / 45 (6.67%)	8 / 86 (9.30%)
occurrences (all)	9	4	8
non-pitting oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	37 / 81 (45.68%)	21 / 45 (46.67%)	23 / 86 (26.74%)
occurrences (all)	67	36	33
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences (all)	3	1	1
peripheral swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 81 (7.41%)	1 / 45 (2.22%)	8 / 86 (9.30%)
occurrences (all)	6	2	11

pyrexia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	23 / 81 (28.40%) 51	10 / 45 (22.22%) 12	26 / 86 (30.23%) 49
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	16 / 81 (19.75%) 22	13 / 45 (28.89%) 21	21 / 86 (24.42%) 27
dyspnoea alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	19 / 81 (23.46%) 30	15 / 45 (33.33%) 30	18 / 86 (20.93%) 25
dyspnoea exertional alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	2 / 45 (4.44%) 4	5 / 86 (5.81%) 7
epistaxis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	16 / 81 (19.75%) 19	5 / 45 (11.11%) 6	17 / 86 (19.77%) 22
haemoptysis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 1	0 / 45 (0.00%) 0	1 / 86 (1.16%) 2
hiccups alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	0 / 45 (0.00%) 0	1 / 86 (1.16%) 1
hypoxia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 81 (3.70%) 3	2 / 45 (4.44%) 2	0 / 86 (0.00%) 0
laryngeal haemorrhage alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences (all)	2	1	0
nasal dryness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 81 (11.11%)	4 / 45 (8.89%)	6 / 86 (6.98%)
occurrences (all)	11	4	6
pleural effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	6 / 45 (13.33%)	1 / 86 (1.16%)
occurrences (all)	4	7	1
pneumonitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 81 (8.64%)	3 / 45 (6.67%)	1 / 86 (1.16%)
occurrences (all)	8	3	1
productive cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	4 / 45 (8.89%)	5 / 86 (5.81%)
occurrences (all)	3	6	6
pulmonary embolism			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	1 / 45 (2.22%) 1	1 / 86 (1.16%) 1
upper-airway cough syndrome alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 81 (2.47%) 3	3 / 45 (6.67%) 3	2 / 86 (2.33%) 2
Psychiatric disorders anxiety alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	5 / 81 (6.17%) 5	2 / 45 (4.44%) 2	5 / 86 (5.81%) 5
depression alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 2	0 / 45 (0.00%) 0	2 / 86 (2.33%) 2
insomnia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	15 / 81 (18.52%) 17	6 / 45 (13.33%) 7	7 / 86 (8.14%) 8
nightmare alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	0 / 45 (0.00%) 0	0 / 86 (0.00%) 0
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	13 / 81 (16.05%) 36	8 / 45 (17.78%) 19	16 / 86 (18.60%) 33
aspartate aminotransferase increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	10 / 81 (12.35%) 22	6 / 45 (13.33%) 15	11 / 86 (12.79%) 14
blood alkaline phosphatase increased alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	7 / 81 (8.64%)	11 / 45 (24.44%)	4 / 86 (4.65%)
occurrences (all)	15	22	6
blood bilirubin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences (all)	2	1	0
blood creatinine increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	3 / 45 (6.67%)	4 / 86 (4.65%)
occurrences (all)	6	3	4
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	2	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	4 / 45 (8.89%)	1 / 86 (1.16%)
occurrences (all)	5	4	4
haemoglobin decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	2	0	0
international normalised ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	2 / 45 (4.44%)	0 / 86 (0.00%)
occurrences (all)	0	2	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 81 (9.88%)	5 / 45 (11.11%)	9 / 86 (10.47%)
occurrences (all)	31	32	33
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	16 / 81 (19.75%)	20 / 45 (44.44%)	14 / 86 (16.28%)
occurrences (all)	44	72	32
platelet count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	19 / 81 (23.46%)	15 / 45 (33.33%)	16 / 86 (18.60%)
occurrences (all)	50	44	46
transaminases increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences (all)	0	0	1
weight decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 81 (6.17%)	3 / 45 (6.67%)	6 / 86 (6.98%)
occurrences (all)	9	4	14
weight increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 81 (8.64%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences (all)	11	0	1
white blood cell count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	12 / 81 (14.81%)	12 / 45 (26.67%)	12 / 86 (13.95%)
occurrences (all)	50	63	43
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	2 / 45 (4.44%)	2 / 86 (2.33%)
occurrences (all)	1	4	3
infusion related reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	4 / 86 (4.65%)
occurrences (all)	3	0	5
meniscus injury			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	0 / 45 (0.00%) 0	0 / 86 (0.00%) 0
wound complication alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	0 / 45 (0.00%) 0	0 / 86 (0.00%) 0
Cardiac disorders atrial fibrillation alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	0 / 45 (0.00%) 0	1 / 86 (1.16%) 1
sinus tachycardia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 81 (3.70%) 5	3 / 45 (6.67%) 3	5 / 86 (5.81%) 8
tachycardia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 81 (3.70%) 3	2 / 45 (4.44%) 2	3 / 86 (3.49%) 3
Nervous system disorders dizziness alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	11 / 81 (13.58%) 26	3 / 45 (6.67%) 4	9 / 86 (10.47%) 12
dysgeusia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	12 / 81 (14.81%) 20	13 / 45 (28.89%) 21	11 / 86 (12.79%) 11
headache alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	15 / 81 (18.52%) 23	6 / 45 (13.33%) 7	13 / 86 (15.12%) 15
memory impairment alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 81 (1.23%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences (all)	1	1	0
neuropathy peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 81 (8.64%)	0 / 45 (0.00%)	5 / 86 (5.81%)
occurrences (all)	10	0	5
paraesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	4 / 45 (8.89%)	3 / 86 (3.49%)
occurrences (all)	4	5	3
peripheral motor neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	1 / 45 (2.22%)	3 / 86 (3.49%)
occurrences (all)	6	2	8
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	10 / 81 (12.35%)	10 / 45 (22.22%)	13 / 86 (15.12%)
occurrences (all)	15	20	31
sciatica			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences (all)	0	1	1
syncope			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	2 / 45 (4.44%)	2 / 86 (2.33%)
occurrences (all)	4	2	6
taste disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences (all)	5	0	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	43 / 81 (53.09%)	33 / 45 (73.33%)	47 / 86 (54.65%)
occurrences (all)	168	145	147
leukopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 81 (8.64%)	1 / 45 (2.22%)	3 / 86 (3.49%)
occurrences (all)	13	4	6
neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	20 / 81 (24.69%)	6 / 45 (13.33%)	24 / 86 (27.91%)
occurrences (all)	55	6	43
neutrophilia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	10 / 81 (12.35%)	9 / 45 (20.00%)	13 / 86 (15.12%)
occurrences (all)	21	18	21
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences (all)	1	2	0
Eye disorders			
dry eye			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	2 / 45 (4.44%)	0 / 86 (0.00%)
occurrences (all)	2	2	0
lacrimation increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	3 / 45 (6.67%)	3 / 86 (3.49%)
occurrences (all)	4	3	3
photopsia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	3 / 45 (6.67%)	2 / 86 (2.33%)
occurrences (all)	5	3	2
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	5 / 45 (11.11%)	1 / 86 (1.16%)
occurrences (all)	3	5	1
abdominal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 81 (11.11%)	7 / 45 (15.56%)	10 / 86 (11.63%)
occurrences (all)	11	12	10
abdominal pain upper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	0 / 45 (0.00%)	2 / 86 (2.33%)
occurrences (all)	5	0	2
anorectal discomfort			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences (all)	0	1	0
aphthous ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	21 / 81 (25.93%)	12 / 45 (26.67%)	20 / 86 (23.26%)
occurrences (all)	29	14	24
diarrhoea			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	36 / 81 (44.44%)	21 / 45 (46.67%)	30 / 86 (34.88%)
occurrences (all)	84	42	50
dry mouth			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 81 (6.17%)	6 / 45 (13.33%)	3 / 86 (3.49%)
occurrences (all)	5	6	3
dyspepsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 81 (7.41%)	2 / 45 (4.44%)	8 / 86 (9.30%)
occurrences (all)	9	2	9
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	6 / 45 (13.33%)	5 / 86 (5.81%)
occurrences (all)	0	7	5
haemorrhoids			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	3 / 45 (6.67%)	4 / 86 (4.65%)
occurrences (all)	1	3	4
intestinal fistula			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	38 / 81 (46.91%)	20 / 45 (44.44%)	40 / 86 (46.51%)
occurrences (all)	59	31	72
oral pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	1 / 45 (2.22%)	3 / 86 (3.49%)
occurrences (all)	1	1	3
proctalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	2 / 86 (2.33%)
occurrences (all)	0	1	2

salivary hypersecretion alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 81 (0.00%) 0	0 / 45 (0.00%) 0	0 / 86 (0.00%) 0
stomatitis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	17 / 81 (20.99%) 34	7 / 45 (15.56%) 18	15 / 86 (17.44%) 26
toothache alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 81 (2.47%) 2	0 / 45 (0.00%) 0	0 / 86 (0.00%) 0
vomiting alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	25 / 81 (30.86%) 30	7 / 45 (15.56%) 8	13 / 86 (15.12%) 17
Skin and subcutaneous tissue disorders			
alopecia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	29 / 81 (35.80%) 35	5 / 45 (11.11%) 5	32 / 86 (37.21%) 44
dermatitis acneiform alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 81 (3.70%) 4	4 / 45 (8.89%) 5	2 / 86 (2.33%) 3
dry skin alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 81 (3.70%) 4	5 / 45 (11.11%) 5	5 / 86 (5.81%) 6
eczema alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 1	0 / 45 (0.00%) 0	1 / 86 (1.16%) 2
erythema alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 81 (6.17%)	0 / 45 (0.00%)	5 / 86 (5.81%)
occurrences (all)	5	0	6
nail discolouration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 81 (6.17%)	3 / 45 (6.67%)	4 / 86 (4.65%)
occurrences (all)	5	3	4
nail dystrophy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	2 / 86 (2.33%)
occurrences (all)	0	0	5
onychomadesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	7 / 45 (15.56%)	3 / 86 (3.49%)
occurrences (all)	1	8	3
palmar-plantar erythrodysaesthesia syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 81 (7.41%)	3 / 45 (6.67%)	4 / 86 (4.65%)
occurrences (all)	16	8	7
pruritus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 81 (9.88%)	2 / 45 (4.44%)	6 / 86 (6.98%)
occurrences (all)	8	3	7
rash			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	15 / 81 (18.52%)	1 / 45 (2.22%)	11 / 86 (12.79%)
occurrences (all)	17	1	17
rash maculo-papular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	10 / 81 (12.35%)	6 / 45 (13.33%)	6 / 86 (6.98%)
occurrences (all)	17	7	7
rash pruritic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences (all)	1	1	0

<p>skin hyperpigmentation</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 81 (3.70%)</p> <p>6</p>	<p>3 / 45 (6.67%)</p> <p>3</p>	<p>4 / 86 (4.65%)</p> <p>4</p>
<p>Renal and urinary disorders</p> <p>chromaturia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>haematuria</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>micturition urgency</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>proteinuria</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 81 (0.00%)</p> <p>0</p> <p>5 / 81 (6.17%)</p> <p>6</p> <p>0 / 81 (0.00%)</p> <p>0</p> <p>3 / 81 (3.70%)</p> <p>3</p>	<p>0 / 45 (0.00%)</p> <p>0</p> <p>0 / 45 (0.00%)</p> <p>0</p> <p>0 / 45 (0.00%)</p> <p>0</p> <p>0 / 45 (0.00%)</p> <p>0</p>	<p>0 / 86 (0.00%)</p> <p>0</p> <p>1 / 86 (1.16%)</p> <p>3</p> <p>0 / 86 (0.00%)</p> <p>0</p> <p>0 / 86 (0.00%)</p> <p>0</p>
<p>Endocrine disorders</p> <p>adrenal insufficiency</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hypothyroidism</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 81 (0.00%)</p> <p>0</p> <p>3 / 81 (3.70%)</p> <p>5</p>	<p>0 / 45 (0.00%)</p> <p>0</p> <p>3 / 45 (6.67%)</p> <p>3</p>	<p>0 / 86 (0.00%)</p> <p>0</p> <p>0 / 86 (0.00%)</p> <p>0</p>
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>13 / 81 (16.05%)</p> <p>24</p>	<p>6 / 45 (13.33%)</p> <p>8</p>	<p>14 / 86 (16.28%)</p> <p>18</p>

back pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	10 / 81 (12.35%)	7 / 45 (15.56%)	7 / 86 (8.14%)
occurrences (all)	16	8	10
bone pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 81 (11.11%)	5 / 45 (11.11%)	7 / 86 (8.14%)
occurrences (all)	10	5	7
coccydynia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	1	0	0
muscle spasms			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 81 (7.41%)	3 / 45 (6.67%)	1 / 86 (1.16%)
occurrences (all)	8	4	1
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 81 (7.41%)	7 / 45 (15.56%)	5 / 86 (5.81%)
occurrences (all)	9	8	10
musculoskeletal chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	2	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	2 / 45 (4.44%)	3 / 86 (3.49%)
occurrences (all)	1	2	6
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	16 / 81 (19.75%)	13 / 45 (28.89%)	11 / 86 (12.79%)
occurrences (all)	27	16	18
pain in extremity			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed occurrences (all)	13 / 81 (16.05%) 16	5 / 45 (11.11%) 7	8 / 86 (9.30%) 9
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences (all)	3	2	1
cellulitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	2 / 45 (4.44%)	2 / 86 (2.33%)
occurrences (all)	5	2	2
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	2 / 86 (2.33%)
occurrences (all)	0	0	2
folliculitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	1	0	0
oral candidiasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	3 / 45 (6.67%)	3 / 86 (3.49%)
occurrences (all)	1	5	4
oral herpes			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	3	0	0
paronychia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences (all)	2	1	1
pneumonia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 81 (6.17%)	5 / 45 (11.11%)	2 / 86 (2.33%)
occurrences (all)	5	6	2
rash pustular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences (all)	4	0	1
respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 81 (1.23%)	1 / 45 (2.22%)	1 / 86 (1.16%)
occurrences (all)	1	1	1
sinusitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 81 (6.17%)	2 / 45 (4.44%)	1 / 86 (1.16%)
occurrences (all)	5	2	1
skin infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 81 (3.70%)	4 / 45 (8.89%)	1 / 86 (1.16%)
occurrences (all)	4	4	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 81 (8.64%)	3 / 45 (6.67%)	14 / 86 (16.28%)
occurrences (all)	9	4	19
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	15 / 81 (18.52%)	3 / 45 (6.67%)	8 / 86 (9.30%)
occurrences (all)	18	4	8
vaginal infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[2]	0 / 48 (0.00%)	0 / 28 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	21 / 81 (25.93%)	11 / 45 (24.44%)	15 / 86 (17.44%)
occurrences (all)	33	14	30
dehydration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 81 (4.94%)	3 / 45 (6.67%)	2 / 86 (2.33%)
occurrences (all)	4	4	2
failure to thrive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
hypercalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	0 / 86 (0.00%)
occurrences (all)	0	2	0
hyperglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 81 (7.41%)	10 / 45 (22.22%)	4 / 86 (4.65%)
occurrences (all)	7	16	4
hyperkalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 81 (2.47%)	0 / 45 (0.00%)	0 / 86 (0.00%)
occurrences (all)	4	0	0
hypernatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	0 / 45 (0.00%)	1 / 86 (1.16%)
occurrences (all)	0	0	1
hyperuricaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 81 (0.00%)	1 / 45 (2.22%)	2 / 86 (2.33%)
occurrences (all)	0	3	4
hypoalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 81 (9.88%)	4 / 45 (8.89%)	2 / 86 (2.33%)
occurrences (all)	9	6	3

hypocalcaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	5 / 81 (6.17%) 6	4 / 45 (8.89%) 5	1 / 86 (1.16%) 1
hypokalaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	6 / 81 (7.41%) 10	9 / 45 (20.00%) 16	10 / 86 (11.63%) 24
hypomagnesaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 81 (1.23%) 1	3 / 45 (6.67%) 5	3 / 86 (3.49%) 5
hyponatraemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	4 / 81 (4.94%) 7	2 / 45 (4.44%) 2	2 / 86 (2.33%) 7
hypophosphataemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 81 (2.47%) 6	1 / 45 (2.22%) 1	4 / 86 (4.65%) 8

Non-serious adverse events	Phase2:Placebo+Gemcitabine+Docetaxel(Olaratumab pretreated)		
Total subjects affected by non-serious adverse events subjects affected / exposed	42 / 43 (97.67%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) tumour pain alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		
Vascular disorders embolism alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2		

<p>embolism venous</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 43 (0.00%)</p> <p>0</p>		
<p>flushing</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>5 / 43 (11.63%)</p> <p>6</p>		
<p>hot flush</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 43 (6.98%)</p> <p>3</p>		
<p>hypertension</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>6 / 43 (13.95%)</p> <p>7</p>		
<p>hypotension</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 43 (4.65%)</p> <p>2</p>		
<p>peripheral venous disease</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 43 (0.00%)</p> <p>0</p>		
<p>phlebitis</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 43 (0.00%)</p> <p>0</p>		
<p>Surgical and medical procedures</p> <p>orchidectomy</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed^[1]</p> <p>occurrences (all)</p>	<p>0 / 15 (0.00%)</p> <p>0</p>		
<p>General disorders and administration site conditions</p>			

asthenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	9		
catheter site pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
chills			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 43 (16.28%)		
occurrences (all)	8		
device related thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
face oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
fatigue			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	23 / 43 (53.49%)		
occurrences (all)	44		
influenza like illness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
infusion site extravasation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
localised oedema			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	2		
malaise			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
non-pitting oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	14 / 43 (32.56%)		
occurrences (all)	21		
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
peripheral swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	11 / 43 (25.58%)		
occurrences (all)	17		
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	9 / 43 (20.93%)		
occurrences (all)	10		
dyspnoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	12 / 43 (27.91%)		
occurrences (all)	18		
dyspnoea exertional			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
epistaxis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 43 (20.93%)		
occurrences (all)	11		
haemoptysis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
hiccups			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	3		
laryngeal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
lower respiratory tract congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		

nasal congestion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	2		
nasal dryness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
oropharyngeal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
pleural effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 43 (9.30%)		
occurrences (all)	4		
pneumonitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
productive cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	4		
pulmonary embolism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
upper-airway cough syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
Psychiatric disorders			

anxiety alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 4		
depression alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2		
insomnia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	10 / 43 (23.26%) 11		
nightmare alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	7 / 43 (16.28%) 20		
aspartate aminotransferase increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 7		
blood alkaline phosphatase increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 6		
blood bilirubin increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		
blood creatinine increased alternative dictionary used:			

MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	9		
blood thyroid stimulating hormone increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	5		
haemoglobin decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
international normalised ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
lymphocyte count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	4		
neutrophil count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 43 (9.30%)		
occurrences (all)	4		
platelet count decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 43 (16.28%)		
occurrences (all)	10		
transaminases increased			
alternative dictionary used: MedDRA 21.0			

<p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>weight decreased</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>5 / 43 (11.63%)</p> <p>occurrences (all)</p> <p>7</p> <p>weight increased</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>1 / 43 (2.33%)</p> <p>occurrences (all)</p> <p>2</p> <p>white blood cell count decreased</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>4 / 43 (9.30%)</p> <p>occurrences (all)</p> <p>6</p>			
<p>Injury, poisoning and procedural complications</p> <p>fall</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>2 / 43 (4.65%)</p> <p>occurrences (all)</p> <p>2</p> <p>infusion related reaction</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>1 / 43 (2.33%)</p> <p>occurrences (all)</p> <p>1</p> <p>meniscus injury</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>wound complication</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Cardiac disorders</p> <p>atrial fibrillation</p> <p>alternative dictionary used: MedDRA 21.0</p>			

<p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>sinus tachycardia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>2 / 43 (4.65%)</p> <p>occurrences (all)</p> <p>4</p>			
<p>tachycardia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>1 / 43 (2.33%)</p> <p>occurrences (all)</p> <p>2</p>			
<p>Nervous system disorders</p> <p>dizziness</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>4 / 43 (9.30%)</p> <p>occurrences (all)</p> <p>4</p> <p>dysgeusia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>14 / 43 (32.56%)</p> <p>occurrences (all)</p> <p>18</p> <p>headache</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>5 / 43 (11.63%)</p> <p>occurrences (all)</p> <p>5</p> <p>memory impairment</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>neuropathy peripheral</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>1 / 43 (2.33%)</p> <p>occurrences (all)</p> <p>1</p> <p>paraesthesia</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
peripheral motor neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 43 (20.93%)		
occurrences (all)	14		
sciatica			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
syncope			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
taste disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	20 / 43 (46.51%)		
occurrences (all)	57		
leukopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	4		
neutropenia			
alternative dictionary used: MedDRA 21.0			

<p>subjects affected / exposed</p> <p>4 / 43 (9.30%)</p> <p>occurrences (all)</p> <p>10</p> <p>neutrophilia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>thrombocytopenia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>6 / 43 (13.95%)</p> <p>occurrences (all)</p> <p>12</p>			
<p>Ear and labyrinth disorders</p> <p>ear pain</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Eye disorders</p> <p>dry eye</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>lacrimation increased</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>3 / 43 (6.98%)</p> <p>occurrences (all)</p> <p>3</p> <p>photopsia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>vision blurred</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>1 / 43 (2.33%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>Gastrointestinal disorders</p> <p>abdominal distension</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
abdominal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 43 (13.95%)		
occurrences (all)	7		
abdominal pain upper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	2		
anorectal discomfort			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
aphthous ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
constipation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	12 / 43 (27.91%)		
occurrences (all)	13		
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	14 / 43 (32.56%)		
occurrences (all)	21		
dry mouth			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 43 (9.30%)		
occurrences (all)	4		
dyspepsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		

gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
haemorrhoids			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
intestinal fistula			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
nausea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	12 / 43 (27.91%)		
occurrences (all)	22		
oral pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 43 (9.30%)		
occurrences (all)	4		
proctalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
salivary hypersecretion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
stomatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	11 / 43 (25.58%)		
occurrences (all)	20		
toothache			
alternative dictionary used: MedDRA 21.0			

<p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>vomiting</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>7 / 43 (16.28%)</p> <p>occurrences (all)</p> <p>13</p>			
<p>Skin and subcutaneous tissue disorders</p> <p>alopecia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>5 / 43 (11.63%)</p> <p>occurrences (all)</p> <p>5</p> <p>dermatitis acneiform</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>2 / 43 (4.65%)</p> <p>occurrences (all)</p> <p>5</p> <p>dry skin</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>5 / 43 (11.63%)</p> <p>occurrences (all)</p> <p>5</p> <p>eczema</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>erythema</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>1 / 43 (2.33%)</p> <p>occurrences (all)</p> <p>1</p> <p>nail discolouration</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>2 / 43 (4.65%)</p> <p>occurrences (all)</p> <p>3</p> <p>nail dystrophy</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
onychomadesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	4		
palmar-plantar erythrodysaesthesia syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	5		
pruritus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
rash			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	3		
rash maculo-papular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
rash pruritic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
skin hyperpigmentation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
chromaturia			
alternative dictionary used: MedDRA 21.0			

<p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>haematuria</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>micturition urgency</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>proteinuria</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>1 / 43 (2.33%)</p> <p>occurrences (all)</p> <p>2</p>			
<p>Endocrine disorders</p> <p>adrenal insufficiency</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>hypothyroidism</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>0 / 43 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>5 / 43 (11.63%)</p> <p>occurrences (all)</p> <p>8</p> <p>back pain</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>3 / 43 (6.98%)</p> <p>occurrences (all)</p> <p>4</p> <p>bone pain</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	6 / 43 (13.95%)		
occurrences (all)	6		
coccydynia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
muscle spasms			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
muscular weakness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 43 (11.63%)		
occurrences (all)	5		
musculoskeletal chest pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
musculoskeletal pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	3		
myalgia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	11 / 43 (25.58%)		
occurrences (all)	19		
pain in extremity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 43 (9.30%)		
occurrences (all)	4		
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
cellulitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
folliculitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
oral candidiasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	4		
oral herpes			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
paronychia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	2		
pneumonia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	4		
rash pustular			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		

respiratory tract infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		
sinusitis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1		
skin infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 3		
upper respiratory tract infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 4		
urinary tract infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1		
vaginal infection alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[2] occurrences (all)	0 / 28 (0.00%) 0		
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	14 / 43 (32.56%) 14		
dehydration alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 3		
failure to thrive alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
hypercalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
hyperglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	4		
hyperkalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
hypernatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
hyperuricaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
hypoalbuminaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 43 (11.63%)		
occurrences (all)	7		
hypocalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	5		
hypokalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 43 (16.28%)		
occurrences (all)	14		

hypomagnesaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	7		
hyponatraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
hypophosphataemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	4		

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.

[2] - 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
15 June 2016	The rationale for amendment (a) was based on feedback received from global regulatory authorities and compliance with local regulatory requirements for submissions. Major changes for amendment (a) included the following: new descriptive language on premedication prior to olaratumab/placebo doses on Days 1 and 8 of Cycle 1 and in subsequent cycles. Clarification was also added related to the olaratumab observation period.
05 January 2017	Amendment (b): The protocol was amended to allow for expansion of the olaratumab 20 mg/kg dose level (Cohort 2) by enrolling approximately 15 additional patients. The rationale for adding an additional 15 patients to Cohort 2 is to confirm the safety of the 20 mg/kg dose level prior to opening the Phase 2 randomized double-blinded portion of the trial.
19 July 2017	Amendment (c): The protocol was amended to enroll an additional cohort of 90 patients previously treated with olaratumab in combination with doxorubicin, in order to evaluate, as secondary objective, the effect of olaratumab as continuation therapy with regimens such as gemcitabine/docetaxel that are customarily administered after maximal doxorubicin dosing. The protocol amendment also added an interim efficacy analysis of all study outcomes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported