Clinical trial results:
A Randomized, Open-Label Phase 1/2 Study Evaluating Ramucirumab in Pediatric Patients and Young Adults With Relapsed, Recurrent, or Refractory Desmoplastic Small Round Cell Tumor

Summary

EudraCT number	2018-004242-42
Trial protocol	FR DE ES NL BE IT
Global end of trial date	

Results information

Result version number	v2
This version publication date	13 August 2025
First version publication date	28 June 2025
Version creation reason	• Correction of full data set Updating Primary Outcome - Progression Free Survival (PFS) information

Trial information

Trial identification

Sponsor protocol code	J1S-MC-JV01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04145349
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17305

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, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

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	14 June 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 June 2024
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

This study is being conducted to test the safety and efficacy of ramucirumab in combination with other chemotherapy in the treatment of relapsed, recurrent, or refractory desmoplastic small round cell tumor (DSRCT) in children and young adults. This trial is part of the CAMPFIRE master protocol (NCT05999994) which is a platform to accelerate the development of new treatments for pediatric and young adult participants with cancer. Your participation in this trial could last 12 months or longer, depending on how you and your tumor respond.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 January 2020
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	Spain: 3
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	United States: 9
Country: Number of subjects enrolled	Japan: 4
Country: Number of subjects enrolled	Australia: 1
Worldwide total number of subjects	30
EEA total number of subjects	10

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	0

months)	
Children (2-11 years)	1
Adolescents (12-17 years)	10
Adults (18-64 years)	19
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Completers included participants who died due to any cause or were alive and on study at conclusion but off treatment.

Pre-assignment

Screening details:

No Text Available

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ramucirumab + Cyclophosphamide + Vinorelbine

Arm description:

Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.
Ramucirumab administered intravenously at a dose of 12 milligrams per kilogram (mg/kg) as a one-hour infusion on days 1 and 15.
Cyclophosphamide administered orally at 25 milligrams per meter square (mg/m2) daily from days 1 to 28.
Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.

Arm type	Experimental
Investigational medicinal product name	Ramucirumab
Investigational medicinal product code	
Other name	LY3009806
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received ramucirumab administered intravenously at a dose of 12 milligrams per kilogram (mg/kg) as a one-hour infusion on days 1 and 15 of a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received cyclophosphamide administered orally at 25 milligrams per meter square (mg/m2) daily from days 1 to 28 of a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.

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

Dosage and administration details:

Participants received vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15 of a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.

Arm title	Cyclophosphamide + Vinorelbine

Arm description:

Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.
Cyclophosphamide administered orally at 25 mg/m² daily from days 1 to 28.
Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.

Arm type	Active comparator
Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received cyclophosphamide administered orally at 25 milligrams per meter square (mg/m2) daily from days 1 to 28 of a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.

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

Dosage and administration details:

Participants received vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15 of a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.

Number of subjects in period 1	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine
Started	20	10
Received at Least One Dose of Study Drug	20	10
Completed	17	8
Not completed	3	2
Lost to Follow-up	-	1
Withdrawal by Subject	3	-
On study treatment (Ongoing)	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Ramucirumab + Cyclophosphamide + Vinorelbine
Reporting group description:	
Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met. Ramucirumab administered intravenously at a dose of 12 milligrams per kilogram (mg/kg) as a one-hour infusion on days 1 and 15. Cyclophosphamide administered orally at 25 milligrams per meter square (mg/m2) daily from days 1 to 28. Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.	
Reporting group title	Cyclophosphamide + Vinorelbine
Reporting group description:	
Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met. Cyclophosphamide administered orally at 25 mg/m² daily from days 1 to 28. Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.	

Reporting group values	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine	Total
Number of subjects	20	10	30
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	19.6	21.4	
standard deviation	± 5.67	± 5.06	-
Gender categorical Units: Subjects			
Female	5	0	5
Male	15	10	25
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	1	4
Not Hispanic or Latino	16	8	24
Unknown or Not Reported	1	1	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	4	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	1	5
White	13	4	17
More than one race	0	0	0
Unknown or Not Reported	1	1	2
Region of Enrollment Units: Subjects			
United States	5	4	9

Japan	1	3	4
Italy	3	1	4
United Kingdom	5	1	6
Australia	1	0	1
Germany	3	0	3
Spain	2	1	3

End points

End points reporting groups

Reporting group title	Ramucirumab + Cyclophosphamide + Vinorelbine

Reporting group description:

Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.
Ramucirumab administered intravenously at a dose of 12 milligrams per kilogram (mg/kg) as a one-hour infusion on days 1 and 15.
Cyclophosphamide administered orally at 25 milligrams per meter square (mg/m2) daily from days 1 to 28.
Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.

Reporting group title	Cyclophosphamide + Vinorelbine

Reporting group description:

Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.
Cyclophosphamide administered orally at 25 mg/m² daily from days 1 to 28.
Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.

Primary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

PFS was defined as the time from randomization to the date of investigator-determined objective progression as defined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, or death from any cause in the absence of disease progression. 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 known to be alive and without disease progression were censored at the date of their last adequate tumor assessment per RECIST 1.1 criteria, or date of randomization (whichever is later). Data are presented as the posterior median with 98% credible interval estimated using Bayesian analysis. Analysis Population Description (APD): All randomized participants who received at least 1 dose of study drug (including the censored participants).

End point type	Primary

End point timeframe:

Randomization to Objective Progression or Death Due to Any Cause (Up To 23 Months)

End point values	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20[1]	10[2]		
Units: Months				
median (confidence interval 98%)	5.69 (3.20 to 10.01)	3.73 (1.76 to 8.29)		

Notes:

[1] - Number of participants censored in Ramucirumab + Cyclophosphamide + Vinorelbine = 4

[2] - Number of participants censored in Cyclophosphamide + Vinorelbine = 2

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The Bayesian analyses below include posterior mean of Hazard ratio, and credible intervals instead of confidence intervals.

Comparison groups	Ramucirumab + Cyclophosphamide + Vinorelbine v Cyclophosphamide + Vinorelbine
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority[3]
Method	Bayesian hierarchical model
Parameter estimate	Posterior Mean Hazard Ratio
Point estimate	0.69
Confidence interval	
level	Other: 98 %
sides	2-sided
lower limit	0.25
upper limit	1.69

Notes:

[3] - The posterior probability treatment difference is 0.864

Secondary: Overall Response Rate (ORR): Percentage of Participants Who Achieved a Complete Response (CR) or Partial Response (PR)

End point title	Overall Response Rate (ORR): Percentage of Participants Who Achieved a Complete Response (CR) or Partial Response (PR)

End point description:

The ORR was defined as the percentage of participants achieving either a CR or PR. Tumor response was assessed based on histology: Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) was used for solid tumors, and Response Assessment in Neuro-Oncology criteria were used for glioblastoma.CR was defined as the disappearance of all target lesions, with any pathological lymph nodes (whether target or non-target) showing a reduction in the short axis to <10 mm. Tumor marker results were required to have normalized. PR was defined as a decrease of at least 30% in the sum of the diameters of target lesions, using baseline diameters as the reference. APD: All randomized participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Randomization until measured progressive disease (Up To 23 Months)

End point values	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	10		
Units: Percentage of participants				
number (confidence interval 80%)	10 (2.7 to 24.5)	10 (1.1 to 33.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR)

End point title	Duration of Response (DoR)

End point description:

DoR is defined as the time from the date that measurement criteria for CR or PR (whichever is first recorded) are first met until the first date that disease is recurrent or objective disease progression is observed, per RECIST 1.1 criteria, or the date of death from any cause in the absence of documented disease progression or recurrence .Participants known to be alive and without disease progression were censored at the date of their last adequate tumor assessment per RECIST 1.1 criteria, or date of randomization (whichever is later). APD: All randomized participants who received at least 1 dose of study drug and who had CR or PR responses (including the censored participants). Number of participants censored in Ramucirumab + Cyclophosphamide + Vinorelbine = 0, Cyclophosphamide + Vinorelbine = 1.

End point type	Secondary

End point timeframe:

Date of CR or PR to Date of Objective Disease Progression or Death Due to Any Cause (Up To 23 Months)

End point values	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[4]	1[5]		
Units: Months				
median (confidence interval 80%)	9.55 (4.89 to 9999)	9999 (9999 to 9999)		

Notes:

[4] - 9999=N/A= There were not enough events to estimate the upper limit of the 80% confidence interval.
[5] - 9999=N/A=DoR couldn't be calculated as the participant did not achieve the event and was censored.

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response (CR) : Percentage of Participants Who Achieved a CR

End point title	Complete Response (CR) : Percentage of Participants Who Achieved a CR

End point description:

CR was defined as the disappearance of all target lesions, with any pathological lymph nodes (whether target or non-target) showing a reduction in the short axis to <10 mm. Tumor marker results were required to have normalized. All randomized participants who received at least one dose of study drug. APD:All randomized participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:

Randomization until measured progressive disease (Up To 23 Months)

End point values	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	10		
Units: Percentage of participants				
number (confidence interval 80%)	5.0 (0.5 to 18.1)	0 (0.0 to 20.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Maximum Serum Concentration of Ramucirumab (Cmax)

End point title	Pharmacokinetics (PK): Maximum Serum Concentration of Ramucirumab (Cmax)[6]

End point description:

Cmax was the concentration of study drug in the blood after the dose is administered. It was measured post-dose and was summarized using descriptive statistics. APD: All randomized participants who received at least one dose of Ramucirumab and had evaluable PK data for this outcome.

End point type	Secondary

End point timeframe:

End of ramucirumab infusion on Day 1 of Cycle 1

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome is planned for Ramucirumab arm only.

End point values	Ramucirumab + Cyclophosphamide + Vinorelbine			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: microgram per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)	238 (± 35)			

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Minimum Serum Concentration of Ramucirumab (Cmin)

End point title	PK: Minimum Serum Concentration of Ramucirumab (Cmin)[7]

End point description:

Cmin was the concentration of study drug in the blood immediately before the next dose was administered. It was measured pre-dose at all visits and was summarized using descriptive statistics. APD: All randomized participants who received at least one dose of Ramucirumab and had evaluable PK

data for this outcome. Number analyzed refers to participants evaluable at specified time points.

End point type	Secondary

End point timeframe:

Prior to ramucirumab infusion on - Day 15 of Cycle 1 and Day 1 of Cycles 2, 4, 7, and 10

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome is planned for Ramucirumab arm only.

End point values	Ramucirumab + Cyclophosphamide + Vinorelbine			
Subject group type	Reporting group			
Number of subjects analysed	13[8]			
Units: microgram per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Day 15 of Cycle 1, Number Analyzed = 13	41.6 (± 57)			
Day 1 of Cycle 2 , Number Analyzed = 9	88.7 (± 47)			
Day 1 of Cycle 4 , Number Analyzed = 7	157 (± 37)			
Day 1 of Cycle 7 , Number Analyzed = 4	155 (± 28)			
Day 1 of Cycle 10 , Number Analyzed = 2	9999 (± 9999)			

Notes:

[8] - 9999=N/A due to insufficient participants. Individual values reported: 151 µg/mL, 207 µg/mL.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Anti-Drug Antibodies (TE-ADA)

End point title	Number of Participants With Treatment-Emergent Anti-Drug Antibodies (TE-ADA)

End point description:

A TE-ADA evaluable participant is considered TE-ADA positive if they have at least one post-baseline ADA titer that is a 4-fold or greater increase from their baseline titer (treatment-boosted); alternatively, if the baseline ADA result is Not Present, the participant is considered TE-ADA positive if there is at least one post-baseline ADA result that is Present with a titer greater than or equal to 1:20 (treatment-induced). APD: All randomized participants who received at least one dose of study drug and had at least one non-missing baseline, post baseline ADA value.

End point type	Secondary

End point timeframe:

Baseline Up to 23 months

End point values	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	5		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up to 23 months

Adverse event reporting additional description:

All randomized participants who received at least one dose of study drug. Participants were analyzed based on the actual treatment they received.
Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Ramucirumab + Cyclophosphamide + Vinorelbine

Reporting group description:

Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.
Ramucirumab administered intravenously at a dose of 12 mg/kg as a one-hour infusion on days 1 and 15.
Cyclophosphamide administered orally at 25 mg/m² daily from days 1 to 28.
Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.

Reporting group title	Cyclophosphamide + Vinorelbine

Reporting group description:

Participants received the following treatments in a 28-day cycle, continuing until disease progression or a criterion for discontinuation was met.
Cyclophosphamide administered orally at 25 mg/m² daily from days 1 to 28.
Vinorelbine administered intravenously at 25 mg/m² on days 1, 8, and 15.

Serious adverse events	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 20 (30.00%)	3 / 10 (30.00%)	
number of deaths (all causes)	12	7	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
post procedural haemorrhage			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular access complication			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
syncope			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyrexia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
febrile neutropenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ascites			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nausea			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
small intestinal obstruction			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
bacteraemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystitis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device related infection			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
influenza			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
viral diarrhoea			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Ramucirumab + Cyclophosphamide + Vinorelbine	Cyclophosphamide + Vinorelbine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	10 / 10 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumour pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 20 (15.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
thrombosis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	

phlebitis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
superficial vein thrombosis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	2 / 10 (20.00%)	
occurrences (all)	2	4	
chills			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
catheter site rash			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
fatigue			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	5 / 20 (25.00%)	2 / 10 (20.00%)	
occurrences (all)	6	3	
early satiety			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
mucosal inflammation			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	4 / 20 (20.00%)	0 / 10 (0.00%)	
occurrences (all)	4	0	
impaired healing			
alternative dictionary used:			

MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
localised oedema			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
malaise			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
thirst			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
pyrexia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	5 / 20 (25.00%)	4 / 10 (40.00%)	
occurrences (all)	7	7	
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
seasonal allergy			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
type iv hypersensitivity reaction			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
vaginal discharge			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed[1]	1 / 5 (20.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	6 / 20 (30.00%)	1 / 10 (10.00%)	
occurrences (all)	6	2	
epistaxis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	8 / 20 (40.00%)	0 / 10 (0.00%)	
occurrences (all)	11	0	
dyspnoea			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
oropharyngeal pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	2 / 10 (20.00%)	
occurrences (all)	2	2	
nasal congestion			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
rhinitis allergic			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
tachypnoea			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
insomnia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Product issues			
device dislocation			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Investigations			
anion gap decreased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
activated partial thromboplastin time prolonged			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 20 (15.00%)	1 / 10 (10.00%)	
occurrences (all)	3	2	
alanine aminotransferase increased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	10 / 20 (50.00%)	2 / 10 (20.00%)	
occurrences (all)	15	7	
blood urea increased			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	6	0		
blood thyroid stimulating hormone increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
blood lactate dehydrogenase increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	2	0		
blood creatinine increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	3 / 20 (15.00%)	0 / 10 (0.00%)		
occurrences (all)	11	0		
aspartate aminotransferase increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	7 / 20 (35.00%)	2 / 10 (20.00%)		
occurrences (all)	11	7		
blood alkaline phosphatase increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	4 / 20 (20.00%)	1 / 10 (10.00%)		
occurrences (all)	6	1		
blood bilirubin increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	2	0		
blood chloride decreased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
blood creatine increased				
alternative dictionary used: MedDRA 27.0				

subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	2	0		
gamma-glutamyltransferase increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	2	0		
glomerular filtration rate decreased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
haemoglobin increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
international normalised ratio increased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	2	0		
lymphocyte count decreased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	5 / 20 (25.00%)	3 / 10 (30.00%)		
occurrences (all)	7	9		
neutrophil count decreased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	10 / 20 (50.00%)	5 / 10 (50.00%)		
occurrences (all)	33	22		
platelet count decreased				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	3 / 20 (15.00%)	1 / 10 (10.00%)		
occurrences (all)	14	2		
weight decreased				
alternative dictionary used: MedDRA 27.0				

subjects affected / exposed	0 / 20 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
weight increased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
white blood cell count decreased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	11 / 20 (55.00%)	6 / 10 (60.00%)	
occurrences (all)	39	26	
Injury, poisoning and procedural complications			
infusion related reaction			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
limb injury			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
wound complication			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
tachycardia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
sinus tachycardia			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
dizziness			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
dysgeusia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
headache			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	10 / 20 (50.00%)	1 / 10 (10.00%)	
occurrences (all)	17	1	
neuropathy peripheral			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	8 / 20 (40.00%)	2 / 10 (20.00%)	
occurrences (all)	13	13	
febrile neutropenia			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
leukopenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
lymphopenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
neutropenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	11 / 20 (55.00%)	1 / 10 (10.00%)	
occurrences (all)	28	3	
thrombocytopenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 20 (15.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
Eye disorders			
eye swelling			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
ocular hyperaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	3 / 10 (30.00%)	
occurrences (all)	2	4	
abdominal pain			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	11 / 20 (55.00%)	2 / 10 (20.00%)		
occurrences (all)	18	2		
ascites				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	2	0		
constipation				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	7 / 20 (35.00%)	3 / 10 (30.00%)		
occurrences (all)	7	3		
anorectal discomfort				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
dry mouth				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
diarrhoea				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	7 / 20 (35.00%)	1 / 10 (10.00%)		
occurrences (all)	12	1		
eructation				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
dyspepsia				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
flatulence				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		

gastritis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
gingival bleeding			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
gingival pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
haemorrhoids			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
nausea			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	4 / 20 (20.00%)	3 / 10 (30.00%)	
occurrences (all)	6	7	
stomatitis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 20 (15.00%)	0 / 10 (0.00%)	
occurrences (all)	4	0	
vomiting			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	6 / 20 (30.00%)	4 / 10 (40.00%)	
occurrences (all)	11	4	
Skin and subcutaneous tissue disorders			
dry skin			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
eczema			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	5	0	
petechiae			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
skin ulcer			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
rash			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
haematuria			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
micturition urgency			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
pollakiuria			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
proteinuria			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	9 / 20 (45.00%)	0 / 10 (0.00%)	
occurrences (all)	14	0	
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
back pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	7 / 20 (35.00%)	2 / 10 (20.00%)	
occurrences (all)	7	3	
myalgia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
muscular weakness			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
pain in extremity			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 20 (15.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
cellulitis			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
cystitis				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
ear lobe infection				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
gingivitis				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	2	0		
klebsiella infection				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
oral herpes				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
nasopharyngitis				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)		
occurrences (all)	1	1		
skin infection				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)		
occurrences (all)	3	0		
urinary tract infection				
alternative dictionary used: MedDRA 27.0				
subjects affected / exposed	2 / 20 (10.00%)	1 / 10 (10.00%)		
occurrences (all)	2	1		

upper respiratory tract infection			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
wound infection			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
decreased appetite			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	3 / 10 (30.00%)	
occurrences (all)	2	3	
hypercalcaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
hyperglycaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
hyperkalaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
hypermagnesaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
hypernatraemia			
alternative dictionary used: MedDRA 27.0			

subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
hyperphosphataemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	2 / 10 (20.00%)	
occurrences (all)	7	2	
hypertriglyceridaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
hypoalbuminaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 20 (15.00%)	1 / 10 (10.00%)	
occurrences (all)	7	1	
hypocalcaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 20 (15.00%)	0 / 10 (0.00%)	
occurrences (all)	12	0	
hypoglycaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
hyponatraemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	5 / 20 (25.00%)	2 / 10 (20.00%)	
occurrences (all)	7	3	
hypomagnesaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
hypokalaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	2 / 20 (10.00%)	2 / 10 (20.00%)	
occurrences (all)	2	2	

hypophosphataemia alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	 0 / 20 (0.00%) 0	 1 / 10 (10.00%) 1	

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: Gender specific events only occurring in female participants have had the number of participants At Risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported