Clinical trial results:
A Phase 2 Study of Cabiralizumab (BMS-986227, FPA008) Administered in Combination with Nivolumab (BMS-936558) with and without Chemotherapy in Patients with Advanced Pancreatic Cancer

Summary

EudraCT number	2018-000339-28
Trial protocol	GB ES DK DE IT
Global end of trial date	01 June 2023

Results information

Result version number	v1 (current)
This version publication date	15 June 2024
First version publication date	15 June 2024

Trial information

Trial identification

Sponsor protocol code	CA025-006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03336216
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 September 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 June 2023
Global end of trial reached?	Yes
Global end of trial date	01 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the PFS of cabiralizumab administered in combination with nivolumab with and without chemotherapy relative to investigator’s choice of chemotherapy in participants with advanced/metastatic pancreatic cancer who progressed on or after the first line of chemotherapy (either gemcitabine-based or 5-FU-based chemotherapy).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 December 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Denmark: 3
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	Japan: 13
Country: Number of subjects enrolled	Korea, Republic of: 7
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Switzerland: 4
Country: Number of subjects enrolled	Taiwan: 7
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 135
Worldwide total number of subjects	205
EEA total number of subjects	32

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)	112
From 65 to 84 years	92
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

205 participants were randomized, 179 were treated.

Period 1

Period 1 title	Randomization
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A: Investigator Choice

Arm description:

Participants receive Investigator choice of chemotherapy:
1) gemcitabine + nab-paclitaxel
2) 5-Fluorouracil/Leucovorin/Irinotecan Liposome

Arm type	Active comparator
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg/m^2

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	ABRAXANE
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous use

Dosage and administration details:

125 mg/m^2

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

Dosage and administration details:

180 mg/m^2

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

Dosage and administration details:

400 mg/m^2

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

Dosage and administration details:

70 mg/m^2 over 90 minutes

Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

400 mg/m^2 bolus and 2400 mg/m^2

Arm title	Arm B: Cabiralizumab + Nivolumab

Arm description:

Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W/

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	BMS-936558
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

480 mg

Investigational medicinal product name	Cabiralizumab
Investigational medicinal product code	
Other name	BMS-986227
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

4 mg/kg

Arm title	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo

Arm description:

Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Gemcitabine + Nab-paclitaxel D1, 8, and 15 Q4W.

Arm type	Experimental
Investigational medicinal product name	Cabiralizumab
Investigational medicinal product code	
Other name	BMS-986227
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

4 mg/kg

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	ABRAXANE
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous use

Dosage and administration details:

125 mg/m^2

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 1000 mg/m^2	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	BMS-936558
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: 480 mg	
Arm title	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Arm description: Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Oxaliplatin/5-Fluorouracil/Leucovorin Q2W	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	BMS-936558
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: 480 mg	
Investigational medicinal product name	Cabiralizumab
Investigational medicinal product code	
Other name	BMS-986227
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: 4 mg/kg	
Investigational medicinal product name	Oxaliplatin
Investigational medicinal product code	
Other name	FOLFOX
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 85 mg/m^2	
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: 400 mg/m^2 bolus and 2400 mg/m^2	
Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	calcium folinate
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
400 mg/m^2

Number of subjects in period 1	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Started	54	54	54
Completed	40	49	48
Not completed	14	5	6
Participant withdrew consent	9	1	-
Adverse event, non-fatal	1	1	-
Not reported	2	-	1
Participant no longer meets study criteria	-	2	4
Other reasons	1	1	1
Lost to follow-up	1	-	-

Number of subjects in period 1	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Started	43
Completed	42
Not completed	1
Participant withdrew consent	-
Adverse event, non-fatal	-
Not reported	-
Participant no longer meets study criteria	1
Other reasons	-
Lost to follow-up	-

Period 2

Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A: Investigator Choice

Arm description:

Participants receive Investigator choice of chemotherapy:
1) gemcitabine + nab-paclitaxel
2) 5-Fluorouracil/Leucovorin/Irinotecan Liposome

Arm type	Active comparator
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg/m^2

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	ABRAXANE
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous use

Dosage and administration details:

125 mg/m^2

Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

400 mg/m^2 bolus and 2400 mg/m^2

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

Dosage and administration details:

400 mg/m^2

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

Dosage and administration details:

70 mg/m^2 over 90 minutes

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

Dosage and administration details:

180 mg/m^2

Arm title	Arm B: Cabiralizumab + Nivolumab

Arm description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W/	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	BMS-936558
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
480 mg	
Investigational medicinal product name	Cabiralizumab
Investigational medicinal product code	
Other name	BMS-986227
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
4 mg/kg	
Arm title	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Arm description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Gemcitabine + Nab-paclitaxel D1, 8, and 15 Q4W.	
Arm type	Experimental
Investigational medicinal product name	Cabiralizumab
Investigational medicinal product code	
Other name	BMS-986227
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
4 mg/kg	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	BMS-936558
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
480 mg	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
1000 mg/m^2	
Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	ABRAXANE
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
125 mg/m^2	
Arm title	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo

Arm description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Oxaliplatin/5-Fluorouracil/Leucovorin Q2W	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	BMS-936558
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
480 mg	
Investigational medicinal product name	Cabiralizumab
Investigational medicinal product code	
Other name	BMS-986227
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
4 mg/kg	
Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	calcium folinate
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
400 mg/m^2	
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
400 mg/m^2 bolus and 2400 mg/m^2	
Investigational medicinal product name	Oxaliplatin
Investigational medicinal product code	
Other name	FOLFOX
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
85 mg/m^2	

Number of subjects in period 2	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Started	40	49	48
Completed	0	1	0
Not completed	40	48	48
Participant request to discontinue treatment	2	1	2

Adverse event, serious fatal	2	3	3
Disease progression	23	34	33
Adverse Event unrelated to study drug	1	1	1
Participant withdrew consent	7	2	3
Adverse event, non-fatal	2	3	4
Study drug toxicity	-	3	2
Participant no longer meets study criteria	-	1	-
Disease Recurrence	1	-	-
Other reasons	2	-	-

Number of subjects in period 2	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Started	42
Completed	1
Not completed	41
Participant request to discontinue treatment	2
Adverse event, serious fatal	4
Disease progression	26
Adverse Event unrelated to study drug	-
Participant withdrew consent	2
Adverse event, non-fatal	4
Study drug toxicity	-
Participant no longer meets study criteria	-
Disease Recurrence	-
Other reasons	3

Baseline characteristics

Reporting groups	
Reporting group title	Arm A: Investigator Choice
Reporting group description:	
Participants receive Investigator choice of chemotherapy: 1) gemcitabine + nab-paclitaxel 2) 5-Fluorouracil/Leucovorin/Irinotecan Liposome	
Reporting group title	Arm B: Cabiralizumab + Nivolumab
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W/	
Reporting group title	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Gemcitabine + Nab-paclitaxel D1, 8, and 15 Q4W.	
Reporting group title	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Oxaliplatin/5-Fluorouracil/Leucovorin Q2W	

Reporting group values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Number of subjects	54	54	54
Age categorical Units: Subjects			
Adults (18-64 years)	31	25	37
From 65-84 years	23	29	17
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	62.7	64.2	59.1
standard deviation	± 8.6	± 9.1	± 9.7
Sex: Female, Male Units: Participants			
Female	26	28	26
Male	28	26	28
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	0	1
Not Hispanic or Latino	46	48	45
Unknown or Not Reported	3	6	8
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	6	8	8
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	3	1

White	40	43	45
More than one race	0	0	0
Unknown or Not Reported	3	0	0

Reporting group values	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo	Total	
Number of subjects	43	205	
Age categorical Units: Subjects			
Adults (18-64 years)	19	112	
From 65-84 years	23	92	
85 years and over	1	1	
Age Continuous Units: Years			
arithmetic mean	64.2		
standard deviation	± 9.6	-	
Sex: Female, Male Units: Participants			
Female	26	106	
Male	17	99	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	6	
Not Hispanic or Latino	41	180	
Unknown or Not Reported	2	19	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	12	34	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	3	12	
White	27	155	
More than one race	0	0	
Unknown or Not Reported	1	4	

End points

End points reporting groups

Reporting group title	Arm A: Investigator Choice
Reporting group description:	
Participants receive Investigator choice of chemotherapy: 1) gemcitabine + nab-paclitaxel 2) 5-Fluorouracil/Leucovorin/Irinotecan Liposome	
Reporting group title	Arm B: Cabiralizumab + Nivolumab
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W/	
Reporting group title	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Gemcitabine + Nab-paclitaxel D1, 8, and 15 Q4W.	
Reporting group title	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Oxaliplatin/5-Fluorouracil/Leucovorin Q2W	
Reporting group title	Arm A: Investigator Choice
Reporting group description:	
Participants receive Investigator choice of chemotherapy: 1) gemcitabine + nab-paclitaxel 2) 5-Fluorouracil/Leucovorin/Irinotecan Liposome	
Reporting group title	Arm B: Cabiralizumab + Nivolumab
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W/	
Reporting group title	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Gemcitabine + Nab-paclitaxel D1, 8, and 15 Q4W.	
Reporting group title	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Reporting group description:	
Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Oxaliplatin/5-Fluorouracil/Leucovorin Q2W	

Primary: Progression Free Survival (PFS) by BICR

End point title	Progression Free Survival (PFS) by BICR
End point description:	
PFS for a participant is defined as the time from randomization date to the date of first objectively documented disease progression by blinded independent central review (BICR) per response evaluation criteria in solid tumors (RECIST) v1.1 or death due to any cause, whichever occurs first. Based on Kaplan-Meier Estimates. Analyzed for all randomized participants with at least one dose of study drug. Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.	
End point type	Primary
End point timeframe:	
From randomization date to the date of first objectively documented disease progression or death (up to approximately 65 months)	

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Months				
median (confidence interval 95%)	3.52 (2.53 to 4.21)	1.92 (1.77 to 2.14)	3.68 (1.94 to 4.83)	3.22 (2.04 to 3.94)

Statistical analyses

Statistical analysis title	Hazard Ratio (Arm A vs B)
Comparison groups	Arm A: Investigator Choice v Arm B: Cabiralizumab + Nivolumab
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.47
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.19
upper limit	1.82

Statistical analysis title	Hazard Ratio (Arm A vs D)
Comparison groups	Arm A: Investigator Choice v Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.78
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.6
upper limit	1.03

Statistical analysis title	Hazard Ratio (Arm A vs C)

Comparison groups	Arm A: Investigator Choice v Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.77
upper limit	1.3

Secondary: Progression Free Survival Rate (PFSR) by BICR

End point title	Progression Free Survival Rate (PFSR) by BICR

End point description:

Progression Free Survival Rates at 6, 9, and 12 months is defined as the percentage of participants who achieve PFS at 6, 9, and 12 months. PFS for a participant is defined as the time from randomization date to the date of first objectively documented disease progression by blinded independent central review (BICR) per response evaluation criteria in solid tumors (RECIST) v1.1 or death due to any cause, whichever occurs first. Based on Kaplan-Meier Estimates. Analyzed for all randomized participants with at least one dose of study drug.

Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

Note: 99999 = Data not calculable (insufficient number of participants with events)

End point type	Secondary

End point timeframe:

At 6, 9, and 12 months

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Percentage of participants				
number (confidence interval 95%)				
6-MONTH	15.5 (4.8 to 31.8)	13.1 (5.3 to 24.4)	21.7 (10.5 to 35.4)	17.7 (7.8 to 30.8)
9-MONTH	5.2 (0.4 to 20.3)	6.5 (1.7 to 16.1)	9.5 (2.6 to 21.8)	10.1 (3.2 to 21.7)
12-MONTH	99999 (99999 to 99999)	2.2 (0.2 to 10.0)	3.2 (0.3 to 13.6)	5.1 (0.9 to 15.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS) by Investigator

End point title	Progression Free Survival (PFS) by Investigator

End point description:

PFS for a participant is defined as the time from randomization date to the date of first objectively documented disease progression by investigator per response evaluation criteria in solid tumors (RECIST) v1.1 or death due to any cause, whichever occurs first. Based on Kaplan-Meier Estimates. Analyzed for all randomized participants with at least one dose of study drug.

Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

End point type	Secondary

End point timeframe:

From randomization date to the date of first objectively documented disease progression or death (up to approximately 65 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Months				
median (confidence interval 95%)	3.38 (1.97 to 3.98)	1.81 (1.74 to 1.97)	3.68 (2.00 to 4.17)	2.92 (1.81 to 3.94)

Statistical analyses

Statistical analysis title	Hazard Ratio (Arm A vs B)
Comparison groups	Arm A: Investigator Choice v Arm B: Cabiralizumab + Nivolumab
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.64
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.33
upper limit	2.02

Statistical analysis title	Hazard Ratio (Arm A vs D)
Comparison groups	Arm A: Investigator Choice v Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.55
upper limit	0.94

Statistical analysis title	Hazard Ratio (Arm A vs C)
Comparison groups	Arm A: Investigator Choice v Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.13
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.87
upper limit	1.46

Secondary: Progression Free Survival Rate (PFSR) by Investigator

End point title	Progression Free Survival Rate (PFSR) by Investigator

End point description:

Progression Free Survival Rates at 6, 9, and 12 months is defined as the percentage of participants who achieve PFS at 6, 9, and 12 months. PFS for a participant is defined as the time from randomization date to the date of first objectively documented disease progression by investigator per response evaluation criteria in solid tumors (RECIST) v1.1 or death due to any cause, whichever occurs first. Based on Kaplan-Meier Estimates. Analyzed for all randomized participants with at least one dose of study drug.

Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

Note: 99999 = Data not available (minimum follow up not reached).

End point type	Secondary

End point timeframe:

At 6, 9, and 12 months

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Percentage of participants				
number (confidence interval 95%)				
6-MONTH	14.9 (4.9 to 30.0)	16.3 (7.6 to 27.9)	17.6 (8.2 to 29.8)	14.7 (6.0 to 27.1)
9-MONTH	11.2 (3.0 to 25.6)	8.2 (2.6 to 17.9)	5.0 (0.9 to 14.7)	7.3 (1.97 to 17.9)
12-MONTH	3.7 (0.3 to 15.9)	99999 (99999 to 99999)	2.5 (0.2 to 11.2)	4.9 (0.9 to 14.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) by BICR

End point title	Objective Response Rate (ORR) by BICR

End point description:

ORR is defined as the percentage of participants whose best overall response (BOR) is either CR or PR by blinded independent central review (BICR) per response evaluation criteria in solid tumors (RECIST) v1.1 based on Clopper-Pearson method. Analyzed for all randomized participants with at least one dose of study drug.

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

End point type	Secondary

End point timeframe:

From randomization to the date of objectively documented progression per RECIST v1.1 or the date of subsequent anti-cancer therapy, whichever occurs first (up to approximately 65 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Percentage of participants				

number (confidence interval 95%)	2.5 (0.1 to 13.2)	4.1 (0.5 to 14.0)	12.5 (4.7 to 25.2)	9.5 (2.7 to 22.6)

Statistical analyses

Statistical analysis title	DIFFERENCE OF ORR (Arm A vs B)
Comparison groups	Arm A: Investigator Choice v Arm B: Cabiralizumab + Nivolumab
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6537 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Strata adjusted difference
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	9

Notes:

[1] - Stratified CMH test stratified by ECOG and prior chemotherapy

Statistical analysis title	DIFFERENCE OF ORR (Arm A vs D)
Comparison groups	Arm A: Investigator Choice v Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5171 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Strata adjusted difference
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	18.1

Notes:

[2] - Stratified CMH test stratified by ECOG and prior chemotherapy

Statistical analysis title	DIFFERENCE OF ORR (Arm A vs C)
Comparison groups	Arm A: Investigator Choice v Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo

Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0951 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Strata adjusted difference
Point estimate	12.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	21.9

Notes:

[3] - Stratified CMH test stratified by ECOG and prior chemotherapy

Secondary: Objective Response Rate (ORR) by Investigator

End point title	Objective Response Rate (ORR) by Investigator

End point description:

ORR is defined as the percentage of participants whose best overall response (BOR) is either CR or PR per response evaluation criteria in solid tumors (RECIST) v1.1 based on Clopper-Pearson method. Analyzed for all randomized participants with at least one dose of study drug.

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

End point type	Secondary

End point timeframe:

From randomization to the date of objectively documented progression per RECIST v1.1 or the date of subsequent anti-cancer therapy, whichever occurs first (up to approximately 65 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Percentage of participants				
number (confidence interval 95%)	5.0 (0.6 to 16.9)	4.1 (0.5 to 14.0)	6.3 (1.3 to 17.2)	4.8 (0.6 to 16.2)

Statistical analyses

Statistical analysis title	DIFFERENCE OF ORR (Arm A vs B)
Comparison groups	Arm A: Investigator Choice v Arm B: Cabiralizumab + Nivolumab

Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8505 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Strata adjusted difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	7.7

Notes:

[4] - Stratified CMH test stratified by ECOG and prior chemotherapy

Statistical analysis title	DIFFERENCE OF ORR (Arm A vs D)
Comparison groups	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo v Arm A: Investigator Choice
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9087 [5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Strata adjusted difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.7
upper limit	12.1

Notes:

[5] - Stratified CMH test stratified by ECOG and prior chemotherapy

Statistical analysis title	DIFFERENCE OF ORR (Arm A vs C)
Comparison groups	Arm A: Investigator Choice v Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8144 [6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Strata adjusted difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.9
upper limit	12.8

Notes:

[6] - Stratified CMH test stratified by ECOG and prior chemotherapy

Secondary: Duration of Response (DOR) by BICR

End point title	Duration of Response (DOR) by BICR

End point description:

DOR is defined as the time between the date of first response and the date of the first objectively documented tumor progression by BICR per RECIST v1.1 or death, whichever occurs first. Estimated using Kaplan-Meier method. Analyzed for all randomized participants (with at least one dose of study drug) with CR or PR.

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

Note: 99999 = Data not calculable (insufficient number of participants with events)

End point type	Secondary

End point timeframe:

From randomization the date of the first objectively documented tumor progression or death, whichever occurs first (up to approximately 65 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	6	4
Units: Months				
median (confidence interval 95%)	99999 (99999 to 99999)	4.2 (3.9 to 99999)	4.6 (3.0 to 99999)	99999 (5.6 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) by Investigator

End point title	Duration of Response (DOR) by Investigator

End point description:

DOR is defined as the time between the date of first response and the date of the first objectively documented tumor progression by investigator per RECIST v1.1 or death, whichever occurs first. Estimated using Kaplan-Meier method. Analyzed for all randomized participants (with at least one dose of study drug) with CR or PR.

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

Note: 99999 = Data not calculable (insufficient number of participants with events)

End point type	Secondary

End point timeframe:

From randomization the date of the first objectively documented tumor progression or death, whichever occurs first (up to approximately 65 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	2
Units: Months				
median (confidence interval 95%)	10.2 (2.7 to 99999)	7.3 (4.5 to 99999)	99999 (3.7 to 99999)	99999 (99999 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS is defined as the time from randomization to the date of death due to any cause. Based on Kaplan-Meier Estimates. Analyzed for all randomized participants with at least one dose of study drug.

End point type	Secondary

End point timeframe:

From randomization to the date of death to any cause (up to approximately 65 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Months				
median (confidence interval 95%)	6.28 (4.53 to 8.11)	4.44 (3.19 to 7.26)	6.72 (4.96 to 8.54)	5.68 (4.57 to 7.33)

Statistical analyses

Statistical analysis title	Hazard Ratio (Arm A vs B)
Comparison groups	Arm A: Investigator Choice v Arm B: Cabiralizumab + Nivolumab

Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Cox proportional hazard
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.96

Statistical analysis title	Hazard Ratio (Arm A vs D)
Comparison groups	Arm A: Investigator Choice v Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Cox proportional hazard
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.46

Statistical analysis title	Hazard Ratio (Arm A vs C)
Comparison groups	Arm A: Investigator Choice v Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Cox proportional hazard
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.86

Secondary: Overall Survival Rates (OSR)

End point title	Overall Survival Rates (OSR)

End point description:

Overall survival at 6 months, 1 year, and 2 years is defined as the percentage of participants who are alive at 6 months, 1 year, and 2 years. Based on Kaplan-Meier Estimates. Analyzed for all randomized participants with at least one dose of study drug.

Note: 99999 = Data estimable (minimum follow up not reached)

End point type	Secondary

End point timeframe:

At 6 months, 1 year, and 2 years

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Percentage of participants				
number (confidence interval 95%)				
6-MONTH	55.8 (38.8 to 69.8)	40.1 (26.1 to 53.8)	54.2 (39.2 to 67.0)	44.8 (29.4 to 59.0)
12-MONTH	14.7 (5.4 to 28.3)	20.1 (10.0 to 32.7)	20.6 (10.6 to 33.0)	17.4 (7.7 to 30.4)
24-MONTH	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants with Adverse Events (AEs)

End point title	The Number of Participants with Adverse Events (AEs)

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. Analyzed for all treated participants.

End point type	Secondary

End point timeframe:

From first dose to 100 days after last dose of study therapy (up to approximately 51 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Participants	40	49	48	42

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants with Serious Adverse Events (SAEs)

End point title	The Number of Participants with Serious Adverse Events (SAEs)

End point description:

A Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is an important medical event. Analyzed for all treated participants.

End point type	Secondary

End point timeframe:

From first dose to 100 days after last dose of study therapy (up to approximately 51 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Participants	23	41	39	33

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants with Adverse Events (AEs) Leading to Discontinuation

End point title	The Number of Participants with Adverse Events (AEs) Leading to Discontinuation

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. Analyzed for all treated participants.

End point type	Secondary

End point timeframe:

From first dose to 100 days after last dose of study therapy (up to approximately 51 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Participants	6	11	11	8

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants who Died

End point title	The Number of Participants who Died

End point description:

The number of participants that died during the study. Analyzed for all treated participants.

End point type	Secondary

End point timeframe:

From first dose to 150 days after last dose of study therapy (up to approximately 53 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	49	48	42
Units: Participants	25	33	30	28

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants who Experienced Abnormal Hepatic Tests

End point title	The Number of Participants who Experienced Abnormal Hepatic Tests

End point description:

The number of treated participants who experienced a laboratory abnormality of the liver during the course of the study. Analyzed for all treated participants with at least one on-treatment hepatic measurement.

Aspartate aminotransferase (AST) Alanine aminotransferase (ALT) Upper Limit of Normal (ULN)

End point type	Secondary

End point timeframe:

From first dose and 100 days after last dose of study therapy (up to approximately 51 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	45	45	41
Units: Participants				
ALT or AST > 3xULN	2	21	37	34
ALT or AST > 5xULN	0	10	19	18
ALT or AST > 10xULN	0	2	6	2
ALT or AST > 12xULN	0	2	4	2
ALT or AST > 20xULN	0	1	1	1
TOTAL BILIRUBIN (=B) > 2xULN	3	3	2	5
ALP > 1.5xULN	27	31	35	30
ALT/AST > 3xULN; =B > 2xULN + ALP <=2ULN/ 3 DAYS	0	1	1	1

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants with On-Treatment Laboratory Abnormalities in Specific Thyroid Tests

End point title	The Number of Participants with On-Treatment Laboratory Abnormalities in Specific Thyroid Tests

End point description:

The number of treated participants who experienced a laboratory abnormality of the thyroid during the course of the study. Analyzed for all treated participants with at least one on-treatment thyroid stimulating hormone (TSH) measurement.

Free T3 (FT3) Free T4 (FT4) Lower Limit of Normal (LLN) Upper Limit of Normal (ULN)

End point type	Secondary

End point timeframe:

From first dose and 100 days after last dose of study therapy (up to approximately 51 months)

End point values	Arm A: Investigator Choice	Arm B: Cabiralizumab + Nivolumab	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	23	25	20
Units: Participants				
TSH > ULN	3	4	10	6
TSH > ULN WITH TSH <= ULN AT BASELINE	0	2	4	2
TSH > ULN WITH AT LEAST ONE T3/T4 TEST VALUE < LLN	0	1	1	0
TSH > ULN WITH ALL T3/T4 TEST VALUES >= LLN	0	0	0	0
TSH > ULN WITH T3/T4 TEST MISSING	0	1	0	0

TSH < LLN	0	0	1	1
TSH < LLN WITH TSH >= LLN AT BASELINE	0	0	0	1
TSH < LLN WITH AT LEAST ONE T3/T4 TEST VALUE > ULN	0	0	0	0
TSH < LLN WITH ALL OTHER T3/T4 TEST VALUES <= ULN	0	0	0	0
TSH < LLN WITH T3/T4 TEST MISSING	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality was assessed from a participants first dose to their study completion (up to approximately 65 months). SAEs and NSAEs were assessed from first dose to 100 days following last dose (up to approximately 51 months)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Arm A1: Investigator Choice - Gem/Nab-Based Chemo

Reporting group description:

Participants receive Investigator choice of chemotherapy:
- gemcitabine + nab-paclitaxel

Reporting group title	Arm A2: Investigator Choice - 5 FU-Based Chemo

Reporting group description:

Participants receive Investigator choice of chemotherapy:
- 5-Fluorouracil/Leucovorin/Irinotecan Liposome

Reporting group title	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo

Reporting group description:

Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Oxaliplatin/5-Fluorouracil/Leucovorin Q2W.

Reporting group title	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo

Reporting group description:

Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W and Gemcitabine + Nab-paclitaxel D1, 8, and 15 Q4W.

Reporting group title	Arm B: Cabiralizumab + Nivolumab

Reporting group description:

Participants receive Cabiralizumab 4MG/KG Q2W + Nivolumab 480 MG Q4W.

Serious adverse events	Arm A1: Investigator Choice - Gem/Nab-Based Chemo	Arm A2: Investigator Choice - 5 FU-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 21 (52.38%)	12 / 19 (63.16%)	33 / 42 (78.57%)
number of deaths (all causes)	19	17	39
number of deaths resulting from adverse events	9	6	20
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Adenocarcinoma gastric			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	8 / 21 (38.10%)	6 / 19 (31.58%)	15 / 42 (35.71%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 15
deaths causally related to treatment / all	0 / 8	0 / 6	0 / 15
Metastatic neoplasm			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oncologic complication			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
Embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capillary leak syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
Face oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	1 / 21 (4.76%)	2 / 19 (10.53%)	5 / 42 (11.90%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
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			
Dyspnoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Liver function test increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Blood bilirubin increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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 electrolytes abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac arrest			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neurotoxicity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Encephalopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Thrombocytopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
Colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Abdominal pain			
subjects affected / exposed	2 / 21 (9.52%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Obstruction gastric			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (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
Immune-mediated hepatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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 pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
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			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Biliary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Clostridium difficile infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (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
Encephalitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Fungal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Escherichia urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (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
Klebsiella sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (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
Oral candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (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
Pneumonia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	6 / 42 (14.29%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 6
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 2
Septic shock			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (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			
Decreased appetite			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (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
Dehydration			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 42 (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
Hyponatraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm C: Cabiralizumab +	Arm B: Cabiralizumab +	

	Nivolumab + Gemcitabine-Based Chemo	Nivolumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	39 / 48 (81.25%)	41 / 49 (83.67%)	
number of deaths (all causes)	46	46	
number of deaths resulting from adverse events	23	29	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	19 / 48 (39.58%)	22 / 49 (44.90%)	
occurrences causally related to treatment / all	0 / 19	0 / 22	
deaths causally related to treatment / all	0 / 19	0 / 22	
Metastatic neoplasm			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oncologic complication			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			

subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Capillary leak syndrome			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
General disorders and administration site conditions			
Face oedema			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthenia			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			

subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 48 (2.08%)	3 / 49 (6.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyrexia			
subjects affected / exposed	3 / 48 (6.25%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumonitis			
subjects affected / exposed	4 / 48 (8.33%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Liver function test increased			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood electrolytes abnormal			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 48 (0.00%)	2 / 49 (4.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocarditis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Neurotoxicity			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Encephalopathy			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Febrile neutropenia			

subjects affected / exposed	2 / 48 (4.17%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	3 / 48 (6.25%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			

subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	2 / 48 (4.17%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal stenosis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	3 / 48 (6.25%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 48 (4.17%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 48 (2.08%)	3 / 49 (6.12%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			

subjects affected / exposed	0 / 48 (0.00%)	2 / 49 (4.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash maculo-papular			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stevens-Johnson syndrome			

subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 48 (8.33%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	2 / 4	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 1	
Haematuria			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	2 / 48 (4.17%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Klebsiella bacteraemia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal infection			

subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	3 / 48 (6.25%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	4 / 48 (8.33%)	3 / 49 (6.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	1 / 48 (2.08%)	2 / 49 (4.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	0 / 48 (0.00%)	2 / 49 (4.08%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Arm A1: Investigator Choice - Gem/Nab-Based Chemo	Arm A2: Investigator Choice - 5 FU-Based Chemo	Arm D: Cabiralizumab + Nivolumab + 5-FU-Based Chemo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 21 (90.48%)	17 / 19 (89.47%)	41 / 42 (97.62%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Deep vein thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	2 / 42 (4.76%)
occurrences (all)	0	1	2
Thrombophlebitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	6 / 42 (14.29%)
occurrences (all)	0	1	7
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 21 (14.29%)	1 / 19 (5.26%)	5 / 42 (11.90%)
occurrences (all)	3	3	8
Catheter site phlebitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Chills			

subjects affected / exposed	5 / 21 (23.81%)	2 / 19 (10.53%)	6 / 42 (14.29%)
occurrences (all)	6	3	8
Face oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	13 / 42 (30.95%)
occurrences (all)	0	0	14
Facial pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	10 / 21 (47.62%)	10 / 19 (52.63%)	23 / 42 (54.76%)
occurrences (all)	13	14	28
Influenza like illness			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Mucosal inflammation			
subjects affected / exposed	2 / 21 (9.52%)	2 / 19 (10.53%)	7 / 42 (16.67%)
occurrences (all)	2	2	11
Non-cardiac chest pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	4 / 21 (19.05%)	0 / 19 (0.00%)	6 / 42 (14.29%)
occurrences (all)	4	0	6
Pain			
subjects affected / exposed	3 / 21 (14.29%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	4	0	1
Peripheral swelling			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	2	0	1
Pyrexia			
subjects affected / exposed	6 / 21 (28.57%)	3 / 19 (15.79%)	15 / 42 (35.71%)
occurrences (all)	11	9	23
Temperature intolerance			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	4
Generalised oedema			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Vaginal discharge			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	4 / 21 (19.05%)	1 / 19 (5.26%)	7 / 42 (16.67%)
occurrences (all)	4	1	7
Dyspnoea			
subjects affected / exposed	4 / 21 (19.05%)	2 / 19 (10.53%)	6 / 42 (14.29%)
occurrences (all)	5	2	6
Cough			
subjects affected / exposed	2 / 21 (9.52%)	2 / 19 (10.53%)	7 / 42 (16.67%)
occurrences (all)	2	2	7
Hiccups			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	2 / 42 (4.76%)
occurrences (all)	0	3	3
Wheezing			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Pulmonary embolism			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Pleural effusion			

subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Nasal congestion			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	2 / 42 (4.76%)
occurrences (all)	1	1	2
Hypoxia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 21 (9.52%)	1 / 19 (5.26%)	2 / 42 (4.76%)
occurrences (all)	2	1	2
Depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Insomnia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	6 / 42 (14.29%)
occurrences (all)	1	1	6
Somnambulism			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	23 / 42 (54.76%)
occurrences (all)	1	0	27
Alanine aminotransferase decreased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	16 / 42 (38.10%)
occurrences (all)	1	0	22
Amylase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Aspartate aminotransferase decreased			

subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 21 (14.29%)	1 / 19 (5.26%)	24 / 42 (57.14%)
occurrences (all)	4	3	26
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 21 (9.52%)	1 / 19 (5.26%)	10 / 42 (23.81%)
occurrences (all)	2	3	11
Blood bilirubin increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Blood creatinine increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	2
Lymphocyte count decreased			
subjects affected / exposed	1 / 21 (4.76%)	3 / 19 (15.79%)	7 / 42 (16.67%)
occurrences (all)	3	3	10
Neutrophil count decreased			
subjects affected / exposed	7 / 21 (33.33%)	4 / 19 (21.05%)	9 / 42 (21.43%)
occurrences (all)	15	6	15
Neutrophil count increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	7 / 21 (33.33%)	3 / 19 (15.79%)	8 / 42 (19.05%)
occurrences (all)	20	5	14
Weight decreased			

subjects affected / exposed	3 / 21 (14.29%)	2 / 19 (10.53%)	4 / 42 (9.52%)
occurrences (all)	3	2	4
White blood cell count decreased			
subjects affected / exposed	4 / 21 (19.05%)	3 / 19 (15.79%)	6 / 42 (14.29%)
occurrences (all)	10	4	13
White blood cell count increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	10 / 42 (23.81%)
occurrences (all)	0	0	11
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences (all)	1	0	2
Fall			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	4 / 42 (9.52%)
occurrences (all)	1	0	5
Infusion related reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	7
Procedural pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			

subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	9 / 42 (21.43%)
occurrences (all)	2	0	9
Headache			
subjects affected / exposed	1 / 21 (4.76%)	3 / 19 (15.79%)	4 / 42 (9.52%)
occurrences (all)	2	9	5
Dysgeusia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 19 (10.53%)	8 / 42 (19.05%)
occurrences (all)	1	2	8
Dizziness			
subjects affected / exposed	4 / 21 (19.05%)	2 / 19 (10.53%)	7 / 42 (16.67%)
occurrences (all)	5	2	7
Polyneuropathy			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	6 / 21 (28.57%)	1 / 19 (5.26%)	7 / 42 (16.67%)
occurrences (all)	6	1	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 21 (42.86%)	5 / 19 (26.32%)	17 / 42 (40.48%)
occurrences (all)	18	8	18
Leukopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	4 / 21 (19.05%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences (all)	6	0	0

Neutropenia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	6 / 42 (14.29%)
occurrences (all)	2	0	10
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Eye disorders			
Periorbital oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	16 / 42 (38.10%)
occurrences (all)	0	0	18
Vision blurred			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Visual impairment			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Vitreous floaters			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Halo vision			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	6 / 21 (28.57%)	4 / 19 (21.05%)	9 / 42 (21.43%)
occurrences (all)	6	7	11
Abdominal pain upper			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	6 / 42 (14.29%)
occurrences (all)	1	1	6
Ascites			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	7 / 21 (33.33%)	8 / 19 (42.11%)	12 / 42 (28.57%)
occurrences (all)	7	10	16
Defaecation urgency			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	5 / 21 (23.81%)	9 / 19 (47.37%)	24 / 42 (57.14%)
occurrences (all)	6	14	40
Dry mouth			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	8 / 42 (19.05%)
occurrences (all)	0	0	8
Dyspepsia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	2	0	3
Haematochezia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Lip dry			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Mouth ulceration			
subjects affected / exposed	2 / 21 (9.52%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	2	1	2
Nausea			
subjects affected / exposed	7 / 21 (33.33%)	9 / 19 (47.37%)	23 / 42 (54.76%)
occurrences (all)	7	11	32
Rectal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Small intestinal haemorrhage			

subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	5 / 21 (23.81%)	2 / 19 (10.53%)	13 / 42 (30.95%)
occurrences (all)	7	3	16
Vomiting			
subjects affected / exposed	9 / 21 (42.86%)	7 / 19 (36.84%)	13 / 42 (30.95%)
occurrences (all)	11	9	18
Flatulence			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	1	1	1
Haemorrhoids			
subjects affected / exposed	3 / 21 (14.29%)	1 / 19 (5.26%)	2 / 42 (4.76%)
occurrences (all)	3	1	2
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Hepatic function abnormal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Portal vein thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Nail discolouration			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	2 / 21 (9.52%)	3 / 19 (15.79%)	3 / 42 (7.14%)
occurrences (all)	2	3	3
Alopecia			

subjects affected / exposed	9 / 21 (42.86%)	2 / 19 (10.53%)	0 / 42 (0.00%)
occurrences (all)	9	2	0
Skin hyperpigmentation			
subjects affected / exposed	2 / 21 (9.52%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	2	1	1
Skin burning sensation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	4 / 21 (19.05%)	1 / 19 (5.26%)	14 / 42 (33.33%)
occurrences (all)	6	1	17
Pruritus			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	6 / 42 (14.29%)
occurrences (all)	1	1	7
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	4 / 42 (9.52%)
occurrences (all)	0	2	4
Rash maculo-papular			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	5 / 42 (11.90%)
occurrences (all)	2	0	6
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Proteinuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 19 (10.53%)	6 / 42 (14.29%)
occurrences (all)	1	2	6
Back pain			

subjects affected / exposed	2 / 21 (9.52%)	3 / 19 (15.79%)	3 / 42 (7.14%)
occurrences (all)	2	3	3
Bone pain			
subjects affected / exposed	2 / 21 (9.52%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	2	3	1
Muscle spasms			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	2	1
Muscular weakness			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	2 / 42 (4.76%)
occurrences (all)	1	1	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	2 / 42 (4.76%)
occurrences (all)	0	1	2
Myalgia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	5 / 42 (11.90%)
occurrences (all)	1	2	7
Pain in extremity			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	1	1	1
Pain in jaw			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Biliary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0

Urinary tract infection			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	3 / 42 (7.14%)
occurrences (all)	3	0	3
Skin infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 19 (10.53%)	8 / 42 (19.05%)
occurrences (all)	2	2	8
Decreased appetite			
subjects affected / exposed	7 / 21 (33.33%)	6 / 19 (31.58%)	23 / 42 (54.76%)
occurrences (all)	9	7	31
Dehydration			
subjects affected / exposed	2 / 21 (9.52%)	2 / 19 (10.53%)	7 / 42 (16.67%)
occurrences (all)	3	2	12
Hyperglycaemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	4 / 42 (9.52%)
occurrences (all)	2	1	4
Hypoalbuminaemia			
subjects affected / exposed	1 / 21 (4.76%)	3 / 19 (15.79%)	5 / 42 (11.90%)
occurrences (all)	2	4	7
Hypokalaemia			
subjects affected / exposed	1 / 21 (4.76%)	8 / 19 (42.11%)	6 / 42 (14.29%)
occurrences (all)	1	11	8
Hypomagnesaemia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 19 (10.53%)	2 / 42 (4.76%)
occurrences (all)	1	2	2
Hyponatraemia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 19 (10.53%)	11 / 42 (26.19%)
occurrences (all)	1	2	15
Hypophosphataemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 19 (10.53%)	11 / 42 (26.19%)
occurrences (all)	0	2	12
Vitamin D deficiency			

subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 42 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Arm C: Cabiralizumab + Nivolumab + Gemcitabine-Based Chemo	Arm B: Cabiralizumab + Nivolumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 48 (97.92%)	46 / 49 (93.88%)	
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences (all)	1	1	
Deep vein thrombosis			
subjects affected / exposed	2 / 48 (4.17%)	1 / 49 (2.04%)	
occurrences (all)	2	1	
Thrombophlebitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	8 / 48 (16.67%)	8 / 49 (16.33%)	
occurrences (all)	8	13	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 48 (10.42%)	3 / 49 (6.12%)	
occurrences (all)	7	3	
Catheter site phlebitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	8 / 48 (16.67%)	2 / 49 (4.08%)	
occurrences (all)	9	2	
Face oedema			
subjects affected / exposed	5 / 48 (10.42%)	3 / 49 (6.12%)	
occurrences (all)	7	3	
Facial pain			

subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	29 / 48 (60.42%)	25 / 49 (51.02%)	
occurrences (all)	36	25	
Influenza like illness			
subjects affected / exposed	5 / 48 (10.42%)	1 / 49 (2.04%)	
occurrences (all)	8	1	
Mucosal inflammation			
subjects affected / exposed	7 / 48 (14.58%)	0 / 49 (0.00%)	
occurrences (all)	7	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	15 / 48 (31.25%)	4 / 49 (8.16%)	
occurrences (all)	16	4	
Pain			
subjects affected / exposed	2 / 48 (4.17%)	4 / 49 (8.16%)	
occurrences (all)	2	4	
Peripheral swelling			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences (all)	1	1	
Pyrexia			
subjects affected / exposed	18 / 48 (37.50%)	12 / 49 (24.49%)	
occurrences (all)	25	16	
Temperature intolerance			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Generalised oedema			
subjects affected / exposed	5 / 48 (10.42%)	0 / 49 (0.00%)	
occurrences (all)	5	0	
Reproductive system and breast disorders			
Pelvic pain			

subjects affected / exposed	2 / 48 (4.17%)	0 / 49 (0.00%)	
occurrences (all)	2	0	
Vulvovaginal dryness			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Vaginal discharge			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	5 / 48 (10.42%)	0 / 49 (0.00%)	
occurrences (all)	7	0	
Dyspnoea			
subjects affected / exposed	9 / 48 (18.75%)	3 / 49 (6.12%)	
occurrences (all)	9	3	
Cough			
subjects affected / exposed	8 / 48 (16.67%)	3 / 49 (6.12%)	
occurrences (all)	10	3	
Hiccups			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Wheezing			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Pulmonary embolism			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences (all)	1	1	
Pneumonitis			
subjects affected / exposed	3 / 48 (6.25%)	4 / 49 (8.16%)	
occurrences (all)	3	4	
Pleural effusion			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	2	
Nasal congestion			

subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences (all)	1	1	
Hypoxia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 48 (4.17%)	1 / 49 (2.04%)	
occurrences (all)	2	1	
Depression			
subjects affected / exposed	6 / 48 (12.50%)	3 / 49 (6.12%)	
occurrences (all)	6	3	
Insomnia			
subjects affected / exposed	3 / 48 (6.25%)	7 / 49 (14.29%)	
occurrences (all)	3	8	
Somnambulism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	18 / 48 (37.50%)	15 / 49 (30.61%)	
occurrences (all)	27	17	
Alanine aminotransferase decreased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	18 / 48 (37.50%)	9 / 49 (18.37%)	
occurrences (all)	29	9	
Amylase increased			
subjects affected / exposed	4 / 48 (8.33%)	0 / 49 (0.00%)	
occurrences (all)	4	0	
Aspartate aminotransferase decreased			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Aspartate aminotransferase increased			

subjects affected / exposed	27 / 48 (56.25%)	14 / 49 (28.57%)	
occurrences (all)	38	15	
Blood alkaline phosphatase increased			
subjects affected / exposed	14 / 48 (29.17%)	9 / 49 (18.37%)	
occurrences (all)	21	9	
Blood bilirubin increased			
subjects affected / exposed	3 / 48 (6.25%)	5 / 49 (10.20%)	
occurrences (all)	4	7	
Blood creatinine increased			
subjects affected / exposed	2 / 48 (4.17%)	4 / 49 (8.16%)	
occurrences (all)	2	5	
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
International normalised ratio increased			
subjects affected / exposed	2 / 48 (4.17%)	0 / 49 (0.00%)	
occurrences (all)	3	0	
Lymphocyte count decreased			
subjects affected / exposed	6 / 48 (12.50%)	4 / 49 (8.16%)	
occurrences (all)	7	4	
Neutrophil count decreased			
subjects affected / exposed	6 / 48 (12.50%)	1 / 49 (2.04%)	
occurrences (all)	7	1	
Neutrophil count increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	18 / 48 (37.50%)	1 / 49 (2.04%)	
occurrences (all)	42	1	
Weight decreased			
subjects affected / exposed	7 / 48 (14.58%)	5 / 49 (10.20%)	
occurrences (all)	7	5	
White blood cell count decreased			
subjects affected / exposed	11 / 48 (22.92%)	2 / 49 (4.08%)	
occurrences (all)	13	4	

White blood cell count increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Blood lactate dehydrogenase increased			
subjects affected / exposed	8 / 48 (16.67%)	7 / 49 (14.29%)	
occurrences (all)	9	7	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	3 / 48 (6.25%)	1 / 49 (2.04%)	
occurrences (all)	3	2	
Fall			
subjects affected / exposed	5 / 48 (10.42%)	2 / 49 (4.08%)	
occurrences (all)	6	3	
Infusion related reaction			
subjects affected / exposed	1 / 48 (2.08%)	4 / 49 (8.16%)	
occurrences (all)	2	4	
Procedural pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	3 / 48 (6.25%)	1 / 49 (2.04%)	
occurrences (all)	3	1	
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Peripheral sensory neuropathy			
subjects affected / exposed	6 / 48 (12.50%)	0 / 49 (0.00%)	
occurrences (all)	6	0	
Headache			
subjects affected / exposed	5 / 48 (10.42%)	6 / 49 (12.24%)	
occurrences (all)	5	7	

Dysgeusia			
subjects affected / exposed	4 / 48 (8.33%)	4 / 49 (8.16%)	
occurrences (all)	4	4	
Dizziness			
subjects affected / exposed	6 / 48 (12.50%)	3 / 49 (6.12%)	
occurrences (all)	7	3	
Polyneuropathy			
subjects affected / exposed	1 / 48 (2.08%)	1 / 49 (2.04%)	
occurrences (all)	1	1	
Post herpetic neuralgia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	13 / 48 (27.08%)	0 / 49 (0.00%)	
occurrences (all)	14	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	34 / 48 (70.83%)	13 / 49 (26.53%)	
occurrences (all)	63	16	
Leukopenia			
subjects affected / exposed	3 / 48 (6.25%)	0 / 49 (0.00%)	
occurrences (all)	6	0	
Lymphopenia			
subjects affected / exposed	3 / 48 (6.25%)	0 / 49 (0.00%)	
occurrences (all)	4	0	
Thrombocytopenia			
subjects affected / exposed	19 / 48 (39.58%)	0 / 49 (0.00%)	
occurrences (all)	34	0	
Neutropenia			
subjects affected / exposed	13 / 48 (27.08%)	0 / 49 (0.00%)	
occurrences (all)	20	0	
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Periorbital oedema			
subjects affected / exposed	21 / 48 (43.75%)	13 / 49 (26.53%)	
occurrences (all)	25	13	
Vision blurred			
subjects affected / exposed	4 / 48 (8.33%)	1 / 49 (2.04%)	
occurrences (all)	4	1	
Visual impairment			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Vitreous floaters			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Halo vision			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 48 (0.00%)	5 / 49 (10.20%)	
occurrences (all)	0	6	
Abdominal pain			
subjects affected / exposed	7 / 48 (14.58%)	15 / 49 (30.61%)	
occurrences (all)	12	16	
Abdominal pain upper			
subjects affected / exposed	1 / 48 (2.08%)	2 / 49 (4.08%)	
occurrences (all)	1	2	
Ascites			
subjects affected / exposed	4 / 48 (8.33%)	4 / 49 (8.16%)	
occurrences (all)	4	4	
Constipation			

subjects affected / exposed	13 / 48 (27.08%)	13 / 49 (26.53%)	
occurrences (all)	15	16	
Defaecation urgency			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	16 / 48 (33.33%)	11 / 49 (22.45%)	
occurrences (all)	23	18	
Dry mouth			
subjects affected / exposed	4 / 48 (8.33%)	5 / 49 (10.20%)	
occurrences (all)	4	5	
Dyspepsia			
subjects affected / exposed	2 / 48 (4.17%)	6 / 49 (12.24%)	
occurrences (all)	2	6	
Haematochezia			
subjects affected / exposed	2 / 48 (4.17%)	1 / 49 (2.04%)	
occurrences (all)	2	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 48 (6.25%)	4 / 49 (8.16%)	
occurrences (all)	3	4	
Lip dry			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Mouth ulceration			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences (all)	4	0	
Nausea			
subjects affected / exposed	16 / 48 (33.33%)	19 / 49 (38.78%)	
occurrences (all)	20	25	
Rectal haemorrhage			
subjects affected / exposed	2 / 48 (4.17%)	0 / 49 (0.00%)	
occurrences (all)	2	0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Stomatitis			

subjects affected / exposed	7 / 48 (14.58%)	4 / 49 (8.16%)	
occurrences (all)	11	5	
Vomiting			
subjects affected / exposed	15 / 48 (31.25%)	11 / 49 (22.45%)	
occurrences (all)	18	17	
Flatulence			
subjects affected / exposed	1 / 48 (2.08%)	2 / 49 (4.08%)	
occurrences (all)	1	2	
Haemorrhoids			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Hepatic function abnormal			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Portal vein thrombosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Nail discolouration			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	2	
Dry skin			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Alopecia			
subjects affected / exposed	13 / 48 (27.08%)	5 / 49 (10.20%)	
occurrences (all)	14	5	
Skin hyperpigmentation			

subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Skin burning sensation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	14 / 48 (29.17%)	11 / 49 (22.45%)	
occurrences (all)	16	13	
Pruritus			
subjects affected / exposed	12 / 48 (25.00%)	8 / 49 (16.33%)	
occurrences (all)	15	11	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Rash maculo-papular			
subjects affected / exposed	11 / 48 (22.92%)	7 / 49 (14.29%)	
occurrences (all)	15	8	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	4 / 48 (8.33%)	0 / 49 (0.00%)	
occurrences (all)	5	0	
Proteinuria			
subjects affected / exposed	4 / 48 (8.33%)	1 / 49 (2.04%)	
occurrences (all)	4	1	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	5 / 48 (10.42%)	2 / 49 (4.08%)	
occurrences (all)	6	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 48 (12.50%)	4 / 49 (8.16%)	
occurrences (all)	13	4	
Back pain			
subjects affected / exposed	5 / 48 (10.42%)	9 / 49 (18.37%)	
occurrences (all)	6	10	
Bone pain			

subjects affected / exposed	1 / 48 (2.08%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Muscle spasms			
subjects affected / exposed	2 / 48 (4.17%)	1 / 49 (2.04%)	
occurrences (all)	2	1	
Muscular weakness			
subjects affected / exposed	5 / 48 (10.42%)	1 / 49 (2.04%)	
occurrences (all)	5	1	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	5 / 48 (10.42%)	2 / 49 (4.08%)	
occurrences (all)	11	2	
Pain in extremity			
subjects affected / exposed	5 / 48 (10.42%)	2 / 49 (4.08%)	
occurrences (all)	6	3	
Pain in jaw			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Candida infection			
subjects affected / exposed	4 / 48 (8.33%)	2 / 49 (4.08%)	
occurrences (all)	5	2	
Biliary tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Endocarditis staphylococcal			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	3 / 48 (6.25%)	5 / 49 (10.20%)	
occurrences (all)	4	5	

Skin infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	6 / 48 (12.50%)	2 / 49 (4.08%)	
occurrences (all)	7	2	
Decreased appetite			
subjects affected / exposed	17 / 48 (35.42%)	11 / 49 (22.45%)	
occurrences (all)	19	11	
Dehydration			
subjects affected / exposed	4 / 48 (8.33%)	9 / 49 (18.37%)	
occurrences (all)	5	12	
Hyperglycaemia			
subjects affected / exposed	7 / 48 (14.58%)	2 / 49 (4.08%)	
occurrences (all)	8	2	
Hypoalbuminaemia			
subjects affected / exposed	7 / 48 (14.58%)	3 / 49 (6.12%)	
occurrences (all)	10	3	
Hypokalaemia			
subjects affected / exposed	9 / 48 (18.75%)	8 / 49 (16.33%)	
occurrences (all)	15	10	
Hypomagnesaemia			
subjects affected / exposed	3 / 48 (6.25%)	4 / 49 (8.16%)	
occurrences (all)	3	12	
Hyponatraemia			
subjects affected / exposed	3 / 48 (6.25%)	7 / 49 (14.29%)	
occurrences (all)	7	14	
Hypophosphataemia			
subjects affected / exposed	9 / 48 (18.75%)	5 / 49 (10.20%)	
occurrences (all)	12	5	
Vitamin D deficiency			
subjects affected / exposed	0 / 48 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 November 2017	1) Expanded rationale for combining immunotherapy and chemotherapy agents 2) Removed criteria excluding participants who had any GI surgery and an inability to tolerate oral medication 3) Added criteria for permanent dose discontinuation and exceptions 4)Added Cycle 2 and Cycle 3 168 hour post dose time point PK collection for cabiralizumab and nivolumab
24 February 2018	1) Removal the cross over post disease progression for participants treated with chemotherapy only. 2) Patient-reported outcomes added to on-treatment, safety follow-up and long term follow-up assessments. 3) Additional data added to support the combination of cabiralizumab and nivolumab.
09 March 2018	1) Updated eligible participants 2) All participants must have fresh tumor biopsy taken during screening. 3) Added analysis of anti-tumor activity in the gut microbiome 4) Patient-reported outcomes added to on-treatment assessments 5) If ONIVYDE-based regimen is not available per institution/country guidelines, FOLFIRI can be used in Arm A. 6) Adequate organ function is defined as ALT and AST < 2 x ULN
17 June 2019	1) Clarified that BICR will be used to assess the primary endpoint of PFS per RECIST v1.1. 2) Clarified the assessment (Investigator/BICR) used for each efficacy evaluation included as a secondary endpoint. 3) Time of on-treatment biopsy was changed to an earlier time point on Cycle 2 Day 8.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported