Clinical trial results:
An Open-Label Randomized Phase III Trial of BMS-936558 (Nivolumab) versus Docetaxel in Previously Treated Metastatic Non-squamous Non-small cell Lung Cancer (NSCLC)

Summary

EudraCT number	2012-002472-14
Trial protocol	DE AT ES HU CZ IT PL NO
Global end of trial date	17 December 2021

Results information

Result version number	v1 (current)
This version publication date	29 December 2022
First version publication date	29 December 2022

Trial information

Trial identification

Sponsor protocol code	CA209-057

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01673867
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee 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	08 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess overall survival (OS) after administration of BMS-936558 (nivolumab) versus docetaxel in prior platinum-based doublet chemotherapy treated metastatic non-squamous NSCLC participants.

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	02 November 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 9
Country: Number of subjects enrolled	Australia: 16
Country: Number of subjects enrolled	Austria: 10
Country: Number of subjects enrolled	Brazil: 24
Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	Chile: 19
Country: Number of subjects enrolled	Czechia: 5
Country: Number of subjects enrolled	France: 49
Country: Number of subjects enrolled	Germany: 45
Country: Number of subjects enrolled	Hong Kong: 1
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Italy: 43
Country: Number of subjects enrolled	Mexico: 18
Country: Number of subjects enrolled	Norway: 5
Country: Number of subjects enrolled	Peru: 6
Country: Number of subjects enrolled	Poland: 25
Country: Number of subjects enrolled	Romania: 10
Country: Number of subjects enrolled	Russian Federation: 14
Country: Number of subjects enrolled	Singapore: 5
Country: Number of subjects enrolled	Spain: 49

Country: Number of subjects enrolled	Switzerland: 13
Country: Number of subjects enrolled	United States: 205
Worldwide total number of subjects	582
EEA total number of subjects	242

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)	339
From 65 to 84 years	241
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

582 participants were randomized and 555 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	Nivolumab

Arm description:

Nivolumab 3 mg/kg solution administered intravenously every 2 weeks. Eligible participants transitioned to nivolumab 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

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

Dosage and administration details:

Nivolumab at 480mg every 4 weeks

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

Dosage and administration details:

Nivolumab 3 mg/kg solution intravenously every 2 weeks

Arm title	Docetaxel

Arm description:

Docetaxel 75mg/m^2 solution administered intravenously every 3 weeks. Eligible participants transitioned to nivolumab 3 mg/kg every 2 weeks or 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Docetaxel 75 mg/m^2 solution intravenously every 3 weeks

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg solution intravenously every 2 weeks

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

Dosage and administration details:

Nivolumab at 480mg every 4 weeks

Number of subjects in period 1	Nivolumab	Docetaxel
Started	292	290
Completed	287	268
Not completed	5	22
Participant no longer meets study criteria	4	5
Withdrawal by participant	-	12
Adverse event unrelated to study drug	1	-
Lost to follow-up	-	1
Participant request to discontinue study treatment	-	4

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	Nivolumab

Arm description:

Nivolumab 3 mg/kg solution administered intravenously every 2 weeks. Eligible participants transitioned to nivolumab 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

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

Dosage and administration details: Nivolumab at 480mg every 4 weeks	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 3 mg/kg solution intravenously every 2 weeks	
Arm title	Docetaxel
Arm description: Docetaxel 75mg/m^2 solution administered intravenously every 3 weeks. Eligible participants transitioned to nivolumab 3 mg/kg every 2 weeks or 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.	
Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Docetaxel 75 mg/m^2 solution intravenously every 3 weeks	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 3 mg/kg solution intravenously every 2 weeks	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab at 480mg every 4 weeks	

Number of subjects in period 2	Nivolumab	Docetaxel
Started	287	268
Transitioned to Nivolumab 3 mg/kg	0 [1]	17
Transitioned to Nivolumab 480 mg	15	1
Completed	2	0
Not completed	285	268
Adverse event, serious fatal	2	3
Maximum clinical benefit	1	10
Withdrawal by participant	5	5

Participant no longer meets study criteria	2	-
Other reason	11	2
Adverse event unrelated to study drug	23	10
Study Drug Toxicity	23	43
Disease Progression	208	178
Participant request to discontinue study treatment	7	17
Administrative reason by sponsor	3	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Participants from this arm can only transition to the Nivolumab 480 mg milestone.

Baseline characteristics

Reporting groups	
Reporting group title	Nivolumab
Reporting group description:	
Nivolumab 3 mg/kg solution administered intravenously every 2 weeks. Eligible participants transitioned to nivolumab 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.	
Reporting group title	Docetaxel
Reporting group description:	
Docetaxel 75mg/m^2 solution administered intravenously every 3 weeks. Eligible participants transitioned to nivolumab 3 mg/kg every 2 weeks or 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.	

Reporting group values	Nivolumab	Docetaxel	Total
Number of subjects	292	290	582
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	184	155	339
From 65-84 years	108	133	241
85 years and over	0	2	2
Age Continuous Units: years			
arithmetic mean	60.9	62.3	
standard deviation	± 9.27	± 9.75	-
Sex: Female, Male Units: Participants			
Female	141	122	263
Male	151	168	319
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	19	16	35
Not Hispanic or Latino	135	141	276
Not Reported	138	133	271
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	9	8	17
Native Hawaiian or Other Pacific Islander	0	1	1
Black or African American	7	9	16
White	267	266	533
Other	8	6	14

End points

End points reporting groups

Reporting group title	Nivolumab
Reporting group description:	
Nivolumab 3 mg/kg solution administered intravenously every 2 weeks. Eligible participants transitioned to nivolumab 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.	
Reporting group title	Docetaxel
Reporting group description:	
Docetaxel 75mg/m^2 solution administered intravenously every 3 weeks. Eligible participants transitioned to nivolumab 3 mg/kg every 2 weeks or 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.	
Reporting group title	Nivolumab
Reporting group description:	
Nivolumab 3 mg/kg solution administered intravenously every 2 weeks. Eligible participants transitioned to nivolumab 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.	
Reporting group title	Docetaxel
Reporting group description:	
Docetaxel 75mg/m^2 solution administered intravenously every 3 weeks. Eligible participants transitioned to nivolumab 3 mg/kg every 2 weeks or 480 mg every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.	

Primary: Overall Survival (OS) Time in Months for All Randomized Participants at Primary Endpoint

End point title	Overall Survival (OS) Time in Months for All Randomized Participants at Primary Endpoint
End point description:	
Overall survival was defined as the time from randomization to the date of death. A participant who has not died will be censored at last known date alive. OS will be followed continuously while participants are on the study drug and every 3 months via in-person or phone contact after participants discontinue the study drug. Median and hazard ratio computed using Kaplan-Meier method.	
End point type	Primary
End point timeframe:	
Randomization until 413 deaths, up to March 2015 (approximately 29 months)	

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	292	290		
Units: Months				
median (confidence interval 95%)	12.19 (9.66 to 14.98)	9.36 (8.05 to 10.68)		

Statistical analyses

Statistical analysis title	Nivolumab over Docetaxel
Comparison groups	Nivolumab v Docetaxel
Number of subjects included in analysis	582
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0015
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95.92 %
sides	2-sided
lower limit	0.59
upper limit	0.89

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

ORR was defined as the percentage of participants whose Best Overall Response (BOR) was a confirmed Complete Response (CR) or Partial Response (PR). BOR was defined as the best investigator-assessed response designation, recorded between the date of randomization and the date of objectively documented progression per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) or the date of subsequent anti-cancer therapy (excluding on-treatment palliative radiotherapy of non-target bone lesions or Central Nervous System (CNS) lesions), whichever occurred first. CR = Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. PR = At least a 30% decrease in the sum of diameters of target lesions, taking, as reference, the baseline sum diameters. CR+PR, confidence interval based on the Clopper and Pearson method.

End point type	Secondary

End point timeframe:

From randomization to date of objectively documented progression (up to approximately 110 months)

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	292	290		
Units: Percentage of participants				
number (confidence interval 95%)	19.5 (15.1 to 24.5)	12.8 (9.1 to 17.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time To Objective Response (TTOR)

End point title	Time To Objective Response (TTOR)

End point description:

Time to Objective Response for participants demonstrating a response (either CR or PR) was defined as the time from the date of randomization to the date of the first confirmed 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.; PR = At least a 30% decrease in the sum of diameters of target lesions, taking, as reference, the baseline sum diameters.

End point type	Secondary

End point timeframe:

From randomization to the date of first confirmed response (up to approximately 110 months)

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	37		
Units: Months				
median (full range (min-max))	2.10 (1.2 to 34.6)	2.73 (1.4 to 31.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Objective Response (DOOR)

End point title	Duration of Objective Response (DOOR)

End point description:

DOR was defined as the time from the date of first confirmed response to the date of the first documented tumor progression (per RECIST v1.1), as determined by the investigator, or death due to any cause, whichever occurred first. DOR was evaluated only for confirmed responders (i.e. participants with confirmed CR or PR). CR = Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.; PR = At least a 30% decrease in the sum of diameters of target lesions, taking, as reference, the baseline sum diameters. Participants who neither progressed nor died were censored on the date of their last evaluable tumor assessment. Median computed using Kaplan-Meier method.

End point type	Secondary

End point timeframe:

From randomization to date of first documented tumor progression or death due to any cause, whichever occurred first (up to approximately 110 months)

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	37		
Units: Months				
median (confidence interval 95%)	17.15 (10.78 to 30.75)	5.55 (4.40 to 7.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)

End point description:

PFS was defined as the time from randomization to the date of the first documented tumor progression (per RECIST 1.1) or death due to any cause. Participants who died without a reported prior progression were considered to have progressed on the date of their death. Progression will be assessed every 6 weeks (from the first on-study radiographic assessment) until disease progression is noted. Progressive disease was defined as least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered progression. Median computed using the Kaplan-Meier method.

End point type	Secondary

End point timeframe:

From randomization to first confirmed response to the date of the first documented tumor progression or death due to any cause, whichever occurred first (up to approximately 110 months)

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	292	290		
Units: Months				
median (confidence interval 95%)	2.33 (2.17 to 3.32)	4.44 (3.45 to 4.86)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Disease-Related Symptom Improvement by Week 12

End point title	Percentage of Participants Experiencing Disease-Related Symptom Improvement by Week 12

End point description:

Disease-related symptom improvement rate by Week 12 was defined as the percentage of randomized participants who had a 10 point or greater decrease from baseline in average symptom burden index score at any time between randomization and Week 12. The participant portion of the Lung Cancer Symptom Scale (LCSS) consisted of 6 symptom-specific questions that addressed cough, dyspnea, fatigue, pain, hemoptysis, and anorexia, plus 3 summary items on symptom distress, interference with activity level, and global health-related Quality of Life (QoL). The scores range from 0 to 100, with 0 representing the best possible score and 100 being the worst possible score. The average symptom burden index score at each assessment was defined as the mean of the 6 symptom-specific questions of the LCSS. 95% CIs were computed using Clopper-Pearson Method.

End point type	Secondary

End point timeframe:

Randomization to Week 12

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	292	290		
Units: Percentage of participants				
number (confidence interval 95%)	17.8 (13.6 to 22.7)	19.7 (15.2 to 24.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) by PD-L1 Expression at Baseline

End point title	Overall Survival (OS) by PD-L1 Expression at Baseline

End point description:

Overall survival was defined as the time from randomization to the date of death. A participant who has not died will be censored at last known date alive. Overall Survival time was measured in months for all randomized participants grouped by their baseline PD-L1 expression level. PD-L1 expression in participants was defined as the percent of disease tumor cells demonstrating plasma membrane PD-L1 staining of any intensity using an immunohistochemistry (IHC) assay. Median computed using the Kaplan-Meier method. NOTE: The number of participants analyzed for each PD-L1 expression parameter may vary depending on the number of participants who had a tumor biopsy assessed for PD-L1 expression.

End point type	Secondary

End point timeframe:

From randomization to the date of death or last known date alive (up to approximately 110 months)

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	137	138		
Units: Months				
median (confidence interval 95%)				
Participants with baseline PD-L1 expression ≥ 5%	19.91 (15.08 to 26.12)	8.11 (6.47 to 10.05)		
Participants with baseline PD-L1 expression < 5%	9.86 (6.93 to 12.81)	10.28 (8.54 to 11.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) by PD-L1 Expression at Baseline

End point title	Objective Response Rate (ORR) by PD-L1 Expression at Baseline

End point description:

ORR was defined as the percentage of all randomized participants whose Best Overall Response (BOR) was a confirmed Complete Response (CR) or Partial Response (PR). CR = Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis

to < 10 mm.; PR = At least a 30% decrease in the sum of diameters of target lesions, taking, as reference, the baseline sum diameters. CR+PR, confidence interval based on the Clopper and Pearson method. ORR was reported for all randomized participants grouped by their baseline PD-L1 expression level. PD-L1 expression in participants was defined as the percent of disease tumor cells demonstrating plasma membrane PD-L1 staining of any intensity using an immunohistochemistry (IHC) assay.

End point type	Secondary

End point timeframe:

From randomization to date of objectively documented progression (up to approximately 110 months)

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	137	138		
Units: Percentage of participants				
number (confidence interval 95%)				
Participants with baseline PD-L1 expression ≥ 5%	36.2 (26.5 to 46.7)	12.8 (6.6 to 21.7)		
Participants with baseline PD-L1 expression < 5%	10.9 (6.3 to 17.4)	14.5 (9.1 to 21.5)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Overall Survival (OS) - Extended Collection

End point title	Overall Survival (OS) - Extended Collection

End point description:

Overall survival was defined as the time from randomization to the date of death. A participant who has not died will be censored at last known date alive. OS will be followed continuously while participants are on the study drug and every 3 months via in-person or phone contact after participants discontinue the study drug. Median computed using Kaplan-Meier method. Note: This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 08-Apr-2022).

End point type	Post-hoc

End point timeframe:

From randomization to the date of death or last known date alive (up to approximately 110 months)

End point values	Nivolumab	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	292	290		
Units: Months				
median (confidence interval 95%)	12.21 (9.66 to 15.08)	9.49 (8.11 to 10.74)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality assessed from first dose to study completion (up to 110 months). SAEs and NSAEs assessed from first dose to 100 days after last dose (up to 108 months).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	NIVOLUMAB 480 mg

Reporting group description:

Nivolumab 480 mg solution administered intravenously every 4 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

Reporting group title	NIVOLUMAB 3 mg/kg

Reporting group description:

Nivolumab 3 mg/kg solution administered intravenously every 2 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

Reporting group title	Extension phase of DOCETAXEL arm: NIVOLUMAB 3 mg/kg

Reporting group description:

Eligible participants from the Docetaxel arm who transitioned to nivolumab 3 mg/kg every 2 weeks via extension phase. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

Reporting group title	Extension phase of DOCETAXEL arm: NIVOLUMAB 480 mg

Reporting group description:

Eligible participants from the Docetaxel arm who transitioned to nivolumab 480 mg every 4 weeks via extension phase. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

Reporting group title	DOCETAXEL

Reporting group description:

Docetaxel 75mg/m^2 solution administered intravenously every 3 weeks. Participants treated until disease progression, discontinuation due to toxicity, withdrawal of consent or end of study.

Serious adverse events	NIVOLUMAB 480 mg	NIVOLUMAB 3 mg/kg	Extension phase of DOCETAXEL arm: NIVOLUMAB 3 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 15 (33.33%)	172 / 287 (59.93%)	9 / 17 (52.94%)
number of deaths (all causes)	2	253	14
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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

Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Breast cancer			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Cancer pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Lung cancer metastatic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 15 (0.00%)	58 / 287 (20.21%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 60	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 50	0 / 1
Malignant pleural effusion			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Metastases to bone			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Metastases to spine			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Neoplasm malignant			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Non-small cell lung cancer			

subjects affected / exposed	0 / 15 (0.00%)	5 / 287 (1.74%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oncologic complication			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Pericardial effusion malignant			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Embolism			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Venous thrombosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Complication associated with device			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Disease progression			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
General physical health deterioration			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Inflammation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Malaise			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 15 (0.00%)	4 / 287 (1.39%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pyrexia			

subjects affected / exposed	0 / 15 (0.00%)	6 / 287 (2.09%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 15 (6.67%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 15 (6.67%)	10 / 287 (3.48%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 6	0 / 0
Dyspnoea at rest			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Hiccups			

subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Pleural effusion			
subjects affected / exposed	0 / 15 (0.00%)	10 / 287 (3.48%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 14	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 15 (0.00%)	5 / 287 (1.74%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	5 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	2 / 15 (13.33%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 15 (0.00%)	13 / 287 (4.53%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	1 / 13	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 15 (0.00%)	10 / 287 (3.48%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 10	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Disorientation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic attack			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Psychotic disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Transaminases increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
White blood cell count decreased			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fall			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (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
Infusion related reaction			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (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
Radius fracture			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Thoracic vertebral fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			

subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Cardiac arrest			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiopulmonary failure			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Pericarditis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Central nervous system necrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Depressed level of consciousness			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Epilepsy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 15 (0.00%)	4 / 287 (1.39%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Hemiplegia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Hydrocephalus			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
IVth nerve paresis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Partial seizures			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Somnolence			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Spinal cord compression			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haematotoxicity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal tear			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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

Abdominal pain upper			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Ascites			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Colitis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	4 / 287 (1.39%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Inguinal hernia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Intestinal perforation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Large intestine perforation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 / 15 (0.00%)	4 / 287 (1.39%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary hypersecretion			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Cholelithiasis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Hepatotoxicity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haematuria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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

Renal failure			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Back pain			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Bone pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Fistula			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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

Joint range of motion decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Osteonecrosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Osteonecrosis of jaw			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Osteoporosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Osteoporotic fracture			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pathological fracture			

subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Spinal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 15 (6.67%)	5 / 287 (1.74%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
COVID-19			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Febrile infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (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 oesophagitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Infected skin ulcer			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Infection			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Nail infection			

subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia			
subjects affected / exposed	1 / 15 (6.67%)	22 / 287 (7.67%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 1	0 / 25	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural pneumonia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (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
Sepsis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
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 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Dehydration			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Hyperglycaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (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
Hypokalaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Serious adverse events	Extension phase of	DOCETAXEL	

	DOCETAXEL arm: NIVOLUMAB 480 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	161 / 268 (60.07%)	
number of deaths (all causes)	0	247	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	40 / 268 (14.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 37	
Malignant pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to central nervous system			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to meninges			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-small cell lung cancer			
subjects affected / exposed	0 / 1 (0.00%)	10 / 268 (3.73%)	
occurrences causally related to treatment / all	0 / 0	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 9	
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oncologic complication			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian neoplasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion malignant			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 4	
Inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 3	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	8 / 268 (2.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 4	
Dyspnoea at rest			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			

subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	5 / 268 (1.87%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 4	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
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 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Panic attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (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 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical condition abnormal			

subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (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			
Craniocerebral injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 1 (100.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
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 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	1 / 1 (100.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery stenosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system necrosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
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	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IVth nerve paresis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			

subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
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 / 1 (0.00%)	0 / 268 (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			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	4 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	24 / 268 (8.96%)	
occurrences causally related to treatment / all	0 / 0	23 / 25	
deaths causally related to treatment / all	0 / 0	1 / 1	
Haematotoxicity			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	8 / 268 (2.99%)	
occurrences causally related to treatment / all	0 / 0	8 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinal tear			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary hypersecretion			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatotoxicity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (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 / 1 (0.00%)	0 / 268 (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	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint range of motion decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis of jaw			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	5 / 268 (1.87%)	
occurrences causally related to treatment / all	0 / 0	3 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
COVID-19			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (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 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal oesophagitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nail infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (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	0 / 1 (0.00%)	18 / 268 (6.72%)	
occurrences causally related to treatment / all	0 / 0	7 / 20	
deaths causally related to treatment / all	0 / 0	0 / 4	
Pneumonia bacterial			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia necrotising			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences causally related to treatment / all	0 / 0	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			

subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
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	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (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 / 1 (0.00%)	0 / 268 (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	0 / 1 (0.00%)	6 / 268 (2.24%)	
occurrences causally related to treatment / all	0 / 0	4 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	NIVOLUMAB 480 mg	NIVOLUMAB 3 mg/kg	Extension phase of DOCETAXEL arm: NIVOLUMAB 3 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 15 (80.00%)	267 / 287 (93.03%)	12 / 17 (70.59%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 15 (13.33%)	14 / 287 (4.88%)	0 / 17 (0.00%)
occurrences (all)	2	15	0
Haematoma			
subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Hot flush			
subjects affected / exposed	1 / 15 (6.67%)	7 / 287 (2.44%)	0 / 17 (0.00%)
occurrences (all)	1	7	0
Hypotension			

subjects affected / exposed	1 / 15 (6.67%)	12 / 287 (4.18%)	0 / 17 (0.00%)
occurrences (all)	2	13	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 15 (6.67%)	60 / 287 (20.91%)	1 / 17 (5.88%)
occurrences (all)	1	72	1
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	96 / 287 (33.45%)	7 / 17 (41.18%)
occurrences (all)	0	118	7
Mucosal inflammation			
subjects affected / exposed	0 / 15 (0.00%)	6 / 287 (2.09%)	1 / 17 (5.88%)
occurrences (all)	0	7	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 15 (0.00%)	17 / 287 (5.92%)	0 / 17 (0.00%)
occurrences (all)	0	17	0
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	36 / 287 (12.54%)	1 / 17 (5.88%)
occurrences (all)	0	47	2
Pain			
subjects affected / exposed	0 / 15 (0.00%)	21 / 287 (7.32%)	0 / 17 (0.00%)
occurrences (all)	0	22	0
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	37 / 287 (12.89%)	1 / 17 (5.88%)
occurrences (all)	0	55	1
Chest discomfort			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Chest pain			
subjects affected / exposed	1 / 15 (6.67%)	11 / 287 (3.83%)	1 / 17 (5.88%)
occurrences (all)	1	12	1
Influenza like illness			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	1 / 17 (5.88%)
occurrences (all)	0	5	1
Nodule			

subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Swelling			
subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 15 (33.33%)	83 / 287 (28.92%)	6 / 17 (35.29%)
occurrences (all)	9	102	8
Dyspnoea			
subjects affected / exposed	1 / 15 (6.67%)	68 / 287 (23.69%)	6 / 17 (35.29%)
occurrences (all)	1	84	6
Dyspnoea exertional			
subjects affected / exposed	0 / 15 (0.00%)	11 / 287 (3.83%)	1 / 17 (5.88%)
occurrences (all)	0	12	1
Haemoptysis			
subjects affected / exposed	0 / 15 (0.00%)	16 / 287 (5.57%)	1 / 17 (5.88%)
occurrences (all)	0	19	1
Nasal congestion			
subjects affected / exposed	1 / 15 (6.67%)	14 / 287 (4.88%)	0 / 17 (0.00%)
occurrences (all)	2	16	0
Oropharyngeal pain			
subjects affected / exposed	1 / 15 (6.67%)	12 / 287 (4.18%)	0 / 17 (0.00%)
occurrences (all)	1	14	0
Productive cough			
subjects affected / exposed	1 / 15 (6.67%)	16 / 287 (5.57%)	1 / 17 (5.88%)
occurrences (all)	1	18	1
Pneumonitis			
subjects affected / exposed	0 / 15 (0.00%)	7 / 287 (2.44%)	1 / 17 (5.88%)
occurrences (all)	0	8	1
Pulmonary embolism			

subjects affected / exposed	0 / 15 (0.00%)	4 / 287 (1.39%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Rhinitis allergic			
subjects affected / exposed	0 / 15 (0.00%)	4 / 287 (1.39%)	1 / 17 (5.88%)
occurrences (all)	0	5	2
Sputum discoloured			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	18 / 287 (6.27%)	0 / 17 (0.00%)
occurrences (all)	0	19	0
Insomnia			
subjects affected / exposed	2 / 15 (13.33%)	25 / 287 (8.71%)	1 / 17 (5.88%)
occurrences (all)	2	27	1
Confusional state			
subjects affected / exposed	1 / 15 (6.67%)	10 / 287 (3.48%)	0 / 17 (0.00%)
occurrences (all)	1	10	0
Depression			
subjects affected / exposed	0 / 15 (0.00%)	8 / 287 (2.79%)	1 / 17 (5.88%)
occurrences (all)	0	9	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	20 / 287 (6.97%)	0 / 17 (0.00%)
occurrences (all)	1	22	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	14 / 287 (4.88%)	0 / 17 (0.00%)
occurrences (all)	1	16	0
Neutrophil count decreased			
subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	0 / 15 (0.00%)	28 / 287 (9.76%)	1 / 17 (5.88%)
occurrences (all)	0	33	1
White blood cell count decreased			

subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 15 (6.67%)	7 / 287 (2.44%)	0 / 17 (0.00%)
occurrences (all)	1	11	0
Blood creatinine increased			
subjects affected / exposed	0 / 15 (0.00%)	11 / 287 (3.83%)	1 / 17 (5.88%)
occurrences (all)	0	13	1
Blood glucose increased			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Blood magnesium decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Haemoglobin decreased			
subjects affected / exposed	1 / 15 (6.67%)	5 / 287 (1.74%)	0 / 17 (0.00%)
occurrences (all)	3	5	0
Lipase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	5	0	0
Weight increased			
subjects affected / exposed	0 / 15 (0.00%)	11 / 287 (3.83%)	1 / 17 (5.88%)
occurrences (all)	0	11	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 15 (6.67%)	5 / 287 (1.74%)	0 / 17 (0.00%)
occurrences (all)	1	6	0
Meniscus injury			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Myocardial infarction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pericardial effusion			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	6 / 287 (2.09%)	1 / 17 (5.88%)
occurrences (all)	0	6	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 15 (6.67%)	30 / 287 (10.45%)	1 / 17 (5.88%)
occurrences (all)	1	35	2
Dysgeusia			
subjects affected / exposed	0 / 15 (0.00%)	6 / 287 (2.09%)	0 / 17 (0.00%)
occurrences (all)	0	7	0
Headache			
subjects affected / exposed	1 / 15 (6.67%)	33 / 287 (11.50%)	1 / 17 (5.88%)
occurrences (all)	1	40	2
Neuropathy peripheral			
subjects affected / exposed	0 / 15 (0.00%)	12 / 287 (4.18%)	2 / 17 (11.76%)
occurrences (all)	0	13	2
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	14 / 287 (4.88%)	0 / 17 (0.00%)
occurrences (all)	0	15	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 15 (0.00%)	7 / 287 (2.44%)	1 / 17 (5.88%)
occurrences (all)	0	8	1
Cognitive disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Epilepsy			

subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 15 (6.67%)	12 / 287 (4.18%)	0 / 17 (0.00%)
occurrences (all)	1	12	0
Memory impairment			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Motor dysfunction			
subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Transient ischaemic attack			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	37 / 287 (12.89%)	0 / 17 (0.00%)
occurrences (all)	0	42	0
Leukopenia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Neutropenia			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences (all)	0	6	0
Lymphadenopathy			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Excessive cerumen production			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Hypoacusis			

subjects affected / exposed	0 / 15 (0.00%)	2 / 287 (0.70%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Tympanic membrane perforation			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	19 / 287 (6.62%)	1 / 17 (5.88%)
occurrences (all)	0	19	1
Abdominal pain upper			
subjects affected / exposed	0 / 15 (0.00%)	11 / 287 (3.83%)	1 / 17 (5.88%)
occurrences (all)	0	13	1
Constipation			
subjects affected / exposed	2 / 15 (13.33%)	69 / 287 (24.04%)	2 / 17 (11.76%)
occurrences (all)	2	76	2
Diarrhoea			
subjects affected / exposed	2 / 15 (13.33%)	57 / 287 (19.86%)	2 / 17 (11.76%)
occurrences (all)	3	97	2
Nausea			
subjects affected / exposed	2 / 15 (13.33%)	72 / 287 (25.09%)	4 / 17 (23.53%)
occurrences (all)	2	102	8
Stomatitis			
subjects affected / exposed	0 / 15 (0.00%)	8 / 287 (2.79%)	1 / 17 (5.88%)
occurrences (all)	0	9	1
Vomiting			
subjects affected / exposed	3 / 15 (20.00%)	44 / 287 (15.33%)	1 / 17 (5.88%)
occurrences (all)	3	62	2
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	7 / 287 (2.44%)	1 / 17 (5.88%)
occurrences (all)	0	8	2
Dysphagia			

subjects affected / exposed	1 / 15 (6.67%)	7 / 287 (2.44%)	1 / 17 (5.88%)
occurrences (all)	1	11	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 15 (0.00%)	11 / 287 (3.83%)	0 / 17 (0.00%)
occurrences (all)	0	11	0
Dry skin			
subjects affected / exposed	0 / 15 (0.00%)	24 / 287 (8.36%)	0 / 17 (0.00%)
occurrences (all)	0	25	0
Erythema			
subjects affected / exposed	1 / 15 (6.67%)	7 / 287 (2.44%)	0 / 17 (0.00%)
occurrences (all)	1	8	0
Pruritus			
subjects affected / exposed	1 / 15 (6.67%)	37 / 287 (12.89%)	2 / 17 (11.76%)
occurrences (all)	1	55	2
Rash			
subjects affected / exposed	3 / 15 (20.00%)	41 / 287 (14.29%)	2 / 17 (11.76%)
occurrences (all)	4	56	2
Night sweats			
subjects affected / exposed	1 / 15 (6.67%)	9 / 287 (3.14%)	0 / 17 (0.00%)
occurrences (all)	1	9	0
Toxic skin eruption			
subjects affected / exposed	0 / 15 (0.00%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 15 (0.00%)	21 / 287 (7.32%)	2 / 17 (11.76%)
occurrences (all)	0	21	2
Hyperthyroidism			
subjects affected / exposed	0 / 15 (0.00%)	4 / 287 (1.39%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 15 (20.00%)	72 / 287 (25.09%)	1 / 17 (5.88%)
occurrences (all)	3	90	1
Back pain			

subjects affected / exposed	2 / 15 (13.33%)	45 / 287 (15.68%)	0 / 17 (0.00%)
occurrences (all)	3	50	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 15 (0.00%)	18 / 287 (6.27%)	0 / 17 (0.00%)
occurrences (all)	0	19	0
Musculoskeletal pain			
subjects affected / exposed	0 / 15 (0.00%)	15 / 287 (5.23%)	0 / 17 (0.00%)
occurrences (all)	0	19	0
Myalgia			
subjects affected / exposed	2 / 15 (13.33%)	20 / 287 (6.97%)	0 / 17 (0.00%)
occurrences (all)	2	24	0
Pain in extremity			
subjects affected / exposed	1 / 15 (6.67%)	29 / 287 (10.10%)	1 / 17 (5.88%)
occurrences (all)	1	35	1
Muscle tightness			
subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Muscular weakness			
subjects affected / exposed	1 / 15 (6.67%)	11 / 287 (3.83%)	0 / 17 (0.00%)
occurrences (all)	1	11	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 15 (6.67%)	2 / 287 (0.70%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Neck pain			
subjects affected / exposed	1 / 15 (6.67%)	8 / 287 (2.79%)	0 / 17 (0.00%)
occurrences (all)	1	9	0
Pain in jaw			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 15 (13.33%)	14 / 287 (4.88%)	1 / 17 (5.88%)
occurrences (all)	2	25	1

Pneumonia			
subjects affected / exposed	2 / 15 (13.33%)	9 / 287 (3.14%)	0 / 17 (0.00%)
occurrences (all)	2	10	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 15 (6.67%)	19 / 287 (6.62%)	2 / 17 (11.76%)
occurrences (all)	1	22	2
Bronchitis			
subjects affected / exposed	2 / 15 (13.33%)	10 / 287 (3.48%)	0 / 17 (0.00%)
occurrences (all)	2	22	0
Campylobacter infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 287 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Candida infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Conjunctivitis			
subjects affected / exposed	1 / 15 (6.67%)	6 / 287 (2.09%)	0 / 17 (0.00%)
occurrences (all)	1	7	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 287 (0.35%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Oral candidiasis			
subjects affected / exposed	0 / 15 (0.00%)	3 / 287 (1.05%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	5 / 287 (1.74%)	1 / 17 (5.88%)
occurrences (all)	0	7	1
Sinusitis			
subjects affected / exposed	1 / 15 (6.67%)	13 / 287 (4.53%)	0 / 17 (0.00%)
occurrences (all)	1	15	0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	13 / 287 (4.53%)	1 / 17 (5.88%)
occurrences (all)	0	14	1
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 15 (0.00%)	91 / 287 (31.71%)	0 / 17 (0.00%)
occurrences (all)	0	103	0
Hyperglycaemia			
subjects affected / exposed	0 / 15 (0.00%)	15 / 287 (5.23%)	0 / 17 (0.00%)
occurrences (all)	0	30	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	6	4	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	4	4	0
Hypocalcaemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 287 (0.35%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	1 / 15 (6.67%)	9 / 287 (3.14%)	0 / 17 (0.00%)
occurrences (all)	1	10	0
Hyponatraemia			
subjects affected / exposed	1 / 15 (6.67%)	10 / 287 (3.48%)	0 / 17 (0.00%)
occurrences (all)	1	12	0
Hypophosphataemia			
subjects affected / exposed	1 / 15 (6.67%)	5 / 287 (1.74%)	0 / 17 (0.00%)
occurrences (all)	1	8	0

Non-serious adverse events	Extension phase of DOCETAXEL arm: NIVOLUMAB 480 mg	DOCETAXEL	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	258 / 268 (96.27%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences (all)	0	4	
Haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Hot flush			

subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	9 / 268 (3.36%)	
occurrences (all)	0	9	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	63 / 268 (23.51%)	
occurrences (all)	0	82	
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	104 / 268 (38.81%)	
occurrences (all)	0	127	
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	19 / 268 (7.09%)	
occurrences (all)	0	21	
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	18 / 268 (6.72%)	
occurrences (all)	0	19	
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	46 / 268 (17.16%)	
occurrences (all)	0	53	
Pain			
subjects affected / exposed	0 / 1 (0.00%)	19 / 268 (7.09%)	
occurrences (all)	0	21	
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	44 / 268 (16.42%)	
occurrences (all)	0	54	
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	6 / 268 (2.24%)	
occurrences (all)	0	6	
Influenza like illness			

subjects affected / exposed	1 / 1 (100.00%)	3 / 268 (1.12%)	
occurrences (all)	1	3	
Nodule			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Swelling			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 1 (100.00%)	67 / 268 (25.00%)	
occurrences (all)	1	75	
Dyspnoea			
subjects affected / exposed	1 / 1 (100.00%)	64 / 268 (23.88%)	
occurrences (all)	1	69	
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	19 / 268 (7.09%)	
occurrences (all)	0	21	
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	15 / 268 (5.60%)	
occurrences (all)	0	18	
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	16 / 268 (5.97%)	
occurrences (all)	0	18	
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	10 / 268 (3.73%)	
occurrences (all)	0	11	
Pneumonitis			

subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences (all)	0	2	
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences (all)	0	4	
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences (all)	0	2	
Sputum discoloured			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	8 / 268 (2.99%)	
occurrences (all)	0	9	
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	23 / 268 (8.58%)	
occurrences (all)	0	23	
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	5 / 268 (1.87%)	
occurrences (all)	0	5	
Depression			
subjects affected / exposed	0 / 1 (0.00%)	10 / 268 (3.73%)	
occurrences (all)	0	10	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	6 / 268 (2.24%)	
occurrences (all)	0	7	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences (all)	0	3	
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	18 / 268 (6.72%)	
occurrences (all)	0	20	
Weight decreased			

subjects affected / exposed	0 / 1 (0.00%)	21 / 268 (7.84%)	
occurrences (all)	0	22	
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	22 / 268 (8.21%)	
occurrences (all)	0	25	
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	6 / 268 (2.24%)	
occurrences (all)	0	6	
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences (all)	0	5	
Blood glucose increased			
subjects affected / exposed	0 / 1 (0.00%)	6 / 268 (2.24%)	
occurrences (all)	0	6	
Blood magnesium decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Haemoglobin decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Weight increased			
subjects affected / exposed	0 / 1 (0.00%)	5 / 268 (1.87%)	
occurrences (all)	0	5	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	2	
Meniscus injury			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 1 (100.00%)	3 / 268 (1.12%)	
occurrences (all)	1	3	
Myocardial infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Pericardial effusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	8 / 268 (2.99%)	
occurrences (all)	0	8	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	25 / 268 (9.33%)	
occurrences (all)	0	28	
Dysgeusia			
subjects affected / exposed	1 / 1 (100.00%)	20 / 268 (7.46%)	
occurrences (all)	1	21	
Headache			
subjects affected / exposed	0 / 1 (0.00%)	35 / 268 (13.06%)	
occurrences (all)	0	48	
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	28 / 268 (10.45%)	
occurrences (all)	0	30	
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	25 / 268 (9.33%)	
occurrences (all)	0	27	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	14 / 268 (5.22%)	
occurrences (all)	0	15	
Cognitive disorder			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Epilepsy			
subjects affected / exposed	1 / 1 (100.00%)	0 / 268 (0.00%)	
occurrences (all)	1	0	
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences (all)	0	5	
Memory impairment			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Motor dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Transient ischaemic attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	68 / 268 (25.37%)	
occurrences (all)	0	81	
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	29 / 268 (10.82%)	
occurrences (all)	0	34	
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	82 / 268 (30.60%)	
occurrences (all)	0	99	
Lymphadenopathy			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Excessive cerumen production			

subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Hypoacusis			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences (all)	0	3	
Tympanic membrane perforation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 1 (0.00%)	22 / 268 (8.21%)	
occurrences (all)	0	23	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	16 / 268 (5.97%)	
occurrences (all)	0	17	
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	14 / 268 (5.22%)	
occurrences (all)	0	15	
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	50 / 268 (18.66%)	
occurrences (all)	0	59	
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	74 / 268 (27.61%)	
occurrences (all)	0	107	
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	85 / 268 (31.72%)	
occurrences (all)	0	123	
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	24 / 268 (8.96%)	
occurrences (all)	0	39	
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	30 / 268 (11.19%)	
occurrences (all)	0	37	
Dyspepsia			

subjects affected / exposed	0 / 1 (0.00%)	12 / 268 (4.48%)	
occurrences (all)	0	12	
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	8 / 268 (2.99%)	
occurrences (all)	0	8	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	70 / 268 (26.12%)	
occurrences (all)	0	71	
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	9 / 268 (3.36%)	
occurrences (all)	0	9	
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	18 / 268 (6.72%)	
occurrences (all)	0	19	
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	7 / 268 (2.61%)	
occurrences (all)	0	7	
Rash			
subjects affected / exposed	0 / 1 (0.00%)	18 / 268 (6.72%)	
occurrences (all)	0	19	
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	5 / 268 (1.87%)	
occurrences (all)	0	5	
Toxic skin eruption			
subjects affected / exposed	1 / 1 (100.00%)	1 / 268 (0.37%)	
occurrences (all)	1	1	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	41 / 268 (15.30%)	
occurrences (all)	0	50	
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	18 / 268 (6.72%)	
occurrences (all)	0	21	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	14 / 268 (5.22%)	
occurrences (all)	0	14	
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	8 / 268 (2.99%)	
occurrences (all)	0	11	
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	35 / 268 (13.06%)	
occurrences (all)	0	49	
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	30 / 268 (11.19%)	
occurrences (all)	0	31	
Muscle tightness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	6 / 268 (2.24%)	
occurrences (all)	0	6	
Musculoskeletal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	2 / 268 (0.75%)	
occurrences (all)	0	2	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	5	
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences (all)	0	4	
Pain in jaw			
subjects affected / exposed	0 / 1 (0.00%)	1 / 268 (0.37%)	
occurrences (all)	0	1	

Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	11 / 268 (4.10%)	
occurrences (all)	0	13	
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	16 / 268 (5.97%)	
occurrences (all)	0	18	
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	13 / 268 (4.85%)	
occurrences (all)	0	19	
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	7 / 268 (2.61%)	
occurrences (all)	0	7	
Campylobacter infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Candida infection			
subjects affected / exposed	0 / 1 (0.00%)	5 / 268 (1.87%)	
occurrences (all)	0	5	
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences (all)	0	5	
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences (all)	0	3	
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences (all)	0	3	
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences (all)	0	5	
Urinary tract infection			

subjects affected / exposed	0 / 1 (0.00%)	9 / 268 (3.36%)	
occurrences (all)	0	9	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 1 (100.00%)	64 / 268 (23.88%)	
occurrences (all)	1	80	
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	15 / 268 (5.60%)	
occurrences (all)	0	17	
Hypercholesterolaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 268 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	6 / 268 (2.24%)	
occurrences (all)	0	8	
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	7 / 268 (2.61%)	
occurrences (all)	0	9	
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 268 (1.49%)	
occurrences (all)	0	6	
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 268 (1.12%)	
occurrences (all)	0	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 July 2013	Inclusion of the approved generic name of "nivolumab" for BMS-936558 throughout the protocol.
22 April 2015	The Data Monitoring Committee (DMC) convened on 16-April-2015 to evaluate data from a planned formal Interim Analysis of overall survival (OS) and declared superiority for OS in participants receiving nivolumab as compared to docetaxel. As a result of the DMC assessment, protocol amended to provide a mechanism for eligible participants originally randomized to the docetaxel treatment Arm B to receive subsequent nivolumab therapy as part of a nivolumab extension phase.
15 September 2016	Protocol amended to include the option for participants receiving nivolumab at the dose of 3mg/ kg every 2 weeks to switch to a flat dose of nivolumab at 480mg every 4 weeks.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported