Clinical trial results:
Non-Comparative, Multi-Cohort, Single Arm, Open-Label, Phase 2 Study of Nivolumab (BMS-936558) in classical Hodgkin Lymphoma (cHL) Subjects (CheckMate 205: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 205)

Summary

EudraCT number	2014-001509-42
Trial protocol	AT BE DE IT NL ES CZ GB
Global end of trial date	27 December 2022

Results information

Result version number	v1 (current)
This version publication date	15 November 2023
First version publication date	15 November 2023

Trial information

Trial identification

Sponsor protocol code	CA209-205

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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	18 January 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the clinical benefit of nivolumab, as measured by objective response rate (ORR) based on independent radiologic review committee (IRRC) assessment in Cohorts A, B and C.
To assess the overall safety and tolerability of nivolumab monotherapy (flat dose 240 mg), followed by the combination of nivolumab and doxorubicin, vinblastine and dacarbazine (AVD) chemotherapy in previously untreated cHL subjects who are newly diagnosed with advanced stage (Stage IIB, III and IV) disease in Cohort D.

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	12 August 2014
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	Austria: 8
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Canada: 26
Country: Number of subjects enrolled	Czechia: 6
Country: Number of subjects enrolled	Germany: 36
Country: Number of subjects enrolled	Italy: 50
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Spain: 26
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	United States: 119
Worldwide total number of subjects	294
EEA total number of subjects	135

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)	282
From 65 to 84 years	10
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

243 participants were treated at 34 sites in 10 countries for cohorts A, B, and C. Cohort D enrolled separately. 51 participants were treated in cohort D for a total of 294 participants treated all together.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin

Arm description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

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

Dosage and administration details:

480 mg flat dose every 4 weeks or 240 mg flat dose every 2 weeks.

Arm title	Cohort B: Post Transplant Brentuximab Vedotin

Arm description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

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

Dosage and administration details:

480 mg flat dose every 4 weeks or 240 mg flat dose every 2 weeks.

Arm title	Cohort C: Brentuximab Vedotin Pre- or Post Transplant

Arm description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

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

Dosage and administration details:

480 mg flat dose every 4 weeks or 240 mg flat dose every 2 weeks.

Arm title	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL

Arm description:

Four doses of nivolumab flat dose 240 mg IV were administered every 2 weeks (monotherapy phase), followed by 12 doses of the combination of AVD (adriamycin/ doxorubicin 25 mg/m2, vinblastine 6 mg/m2, dacarbazine 375 mg/m2) chemotherapy and nivolumab flat dose 240 mg IV for 6 cycles (combination phase).

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

Dosage and administration details:

375 mg/m2 every 15 days for 12 doses

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	BMS-936558
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

480 mg flat dose every 4 weeks or 240 mg flat dose every 2 weeks.

Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25 mg/m2 every 15 days for 12 doses

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

Dosage and administration details:

6 mg/m2 every 15 days for 12 doses

Number of subjects in period 1	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant
Started	63	80	100
N-AVD combination therapy phase	0	0	0 [1]
AVD combination therapy phase	0	0	0 [2]
Completed	0	0	13
Not completed	63	80	87
Poor/Non-Compliance	1	-	2
Other Reasons	14	16	28
Participant Request to Discontinue Study Treatment	5	12	5
Maximum Clinical Benefit	3	-	1
Adverse Event Unrelated to Study Drug	3	3	1
Study Drug Toxicity	6	11	8
Lost to follow-up	1	2	1
Participant no Longer Meets Study Criteria	-	-	-
Participant Withdrew Consent	2	1	1
Disease Progression	28	35	40

Number of subjects in period 1	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL
Started	51
N-AVD combination therapy phase	49
AVD combination therapy phase	1 [3]
Completed	45
Not completed	6
Poor/Non-Compliance	1
Other Reasons	-
Participant Request to Discontinue Study Treatment	1
Maximum Clinical Benefit	-
Adverse Event Unrelated to Study Drug	-
Study Drug Toxicity	1
Lost to follow-up	1
Participant no Longer Meets Study Criteria	1
Participant Withdrew Consent	1
Disease Progression	-

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: Combination therapy was only given to participants in Cohort D

[2] - 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: Combination therapy was only given to participants in Cohort D

[3] - 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: Combination therapy was only given to participants in Cohort D

Baseline characteristics

Reporting groups	
Reporting group title	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin
Reporting group description:	
Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.	
Reporting group title	Cohort B: Post Transplant Brentuximab Vedotin
Reporting group description:	
Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.	
Reporting group title	Cohort C: Brentuximab Vedotin Pre- or Post Transplant
Reporting group description:	
Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.	
Reporting group title	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL
Reporting group description:	
Four doses of nivolumab flat dose 240 mg IV were administered every 2 weeks (monotherapy phase), followed by 12 doses of the combination of AVD (adriamycin/ doxorubicin 25 mg/m2, vinblastine 6 mg/m2, dacarbazine 375 mg/m2) chemotherapy and nivolumab flat dose 240 mg IV for 6 cycles (combination phase).	

Reporting group values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant
Number of subjects	63	80	100
Age categorical Units: Subjects			
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)	62	77	97
From 65-84 years	1	3	3
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	36.3	38.7	36.1
standard deviation	± 12.54	± 13.00	± 12.41

Sex: Female, Male Units: Participants			
Female	29	29	44
Male	34	51	56
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	1	1
Not Hispanic or Latino	30	63	56
Unknown or Not Reported	30	16	43
Race/Ethnicity, Customized Units: Subjects			
White	54	71	86
Black or African	2	4	6
Asian	3	1	5
American Indian or Alaska Native	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Other	4	4	1

Reporting group values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL	Total	
Number of subjects	51	294	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	46	282	
From 65-84 years	3	10	
85 years and over	2	2	
Age Continuous Units: Years			
arithmetic mean	39.0		
standard deviation	± 16.88	-	
Sex: Female, Male Units: Participants			
Female	19	121	
Male	32	173	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	5	
Not Hispanic or Latino	40	189	
Unknown or Not Reported	11	100	
Race/Ethnicity, Customized Units: Subjects			
White	45	256	

Black or African	2	14	
Asian	2	11	
American Indian or Alaska Native	0	2	
Native Hawaiian or Other Pacific Islander	0	0	
Other	2	11	

End points

End points reporting groups

Reporting group title	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort B: Post Transplant Brentuximab Vedotin

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort C: Brentuximab Vedotin Pre- or Post Transplant

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL

Reporting group description:

Four doses of nivolumab flat dose 240 mg IV were administered every 2 weeks (monotherapy phase), followed by 12 doses of the combination of AVD (adriamycin/ doxorubicin 25 mg/m2, vinblastine 6 mg/m2, dacarbazine 375 mg/m2) chemotherapy and nivolumab flat dose 240 mg IV for 6 cycles (combination phase).

Primary: Primary Analysis Objective Response Rate (ORR) based on IRRC assessments in Cohorts A, B, and C

End point title	Primary Analysis Objective Response Rate (ORR) based on IRRC assessments in Cohorts A, B, and C[1][2]

End point description:

ORR is the percent of participants achieving either a complete remission (CR) or partial remission (PR) according to the 2007 IWG criteria. Analyses of efficacy endpoints were performed separately for each cohort, according to IWG 2007. For cohort A and B, if the bone marrow was involved by lymphoma before treatment, the infiltrate must have cleared on repeat bone marrow biopsy. For cohort C, no evidence of FDG-avid disease in bone marrow was required in all participants in lieu of bone marrow aspirate/ biopsy.
CR is the percent of participants with a best overall response (BOR) of CR (disappearance of all evidence of disease) according to the 2007 IWG criteria, based on IRRC assessment.
PR is the percent of participants with a best overall response (BOR) of PR (regression of measurable disease and no new sites) according to the 2007 IWG criteria, based on IRRC assessment.
Confidence interval based on Clopper-Pearson method.

End point type	Primary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, whichever occurred first (up to approximately 28 months)

Notes:

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

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	80	100	
Units: Percentage of Particpants				
number (confidence interval 95%)	65.1 (52.0 to 76.7)	67.5 (56.1 to 77.6)	73.0 (63.2 to 81.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who experienced at least one treatment related grade 3-5 AE in Cohort D

End point title	Number of Participants who experienced at least one treatment related grade 3-5 AE in Cohort D[3][4]

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation subject administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug.

End point type	Primary

End point timeframe:

From first dose of the study therapy phase to 30 days after last dose of study therapy phase [up to cutoff date of 12-Oct-2017] (up to approximately 39 months)

Notes:

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

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Monotherapy	0			
Combination Therapy (receiving AVD or NAVD)	30			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Objective Response based on IRRC assessments in Cohorts A, B, and C

End point title	Duration of Objective Response based on IRRC assessments in Cohorts A, B, and C[5]

End point description:

DOR is the time from first response (complete remission (CR) or partial remission (PR)) to the date of initial objectively documented progression as determined using the 2007 IWG criteria or death due to any cause, whichever occurred first. For participants who neither progressed nor died, the DOR was censored on the date of their last tumor assessment. Participants who started subsequent therapy without a prior reported progression were censored at the last tumor assessments prior to initiation of the subsequent anticancer therapy.
CR is the percent of participants with a best overall response (BOR) of CR (disappearance of all evidence of disease) according to the 2007 IWG criteria, based on IRRC assessment.
PR is the percent of participants with a best overall response (BOR) of PR (regression of measurable disease and no new sites) according to the 2007 IWG criteria, based on IRRC assessment.
Computed using Kaplan-Meier method.
'99999' = NA

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months).

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	57	75	
Units: Months				
median (confidence interval 95%)	26.18 (15.21 to 99999)	16.59 (9.26 to 25.72)	18.17 (11.63 to 30.85)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Complete Remission (CR) based on IRRC assessments for Cohorts A, B, and C

End point title	Duration of Complete Remission (CR) based on IRRC assessments for Cohorts A, B, and C[6]

End point description:

The duration of CR was only evaluated in participants with BOR of CR and was defined as the time from first documentation of CR (the date of first negative FDG-PET scan or the date of first documentation of no disease involvement in the bone marrow (if required), whichever occurred later) to the date of initial objectively documented progression (Any new lesion or increase by >=50% of previously involved sites from nadir) as determined using the 2007 IWG criteria or death due to any cause, whichever occurred first. Censoring was applied as per DOR definition.
Computed using Kaplan-Meier method.
'99999'=NA

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	11	21	
Units: Months				
median (confidence interval 95%)	99999 (18.00 to 99999)	30.32 (2.4 to 99999)	26.41 (7.13 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Remission (CR) Rate based on IRRC assessments in Cohorts A, B, and C

End point title	Complete Remission (CR) Rate based on IRRC assessments in Cohorts A, B, and C[7]

End point description:

The CR rate was defined as the percent of participants with a BOR of CR (disappearance of all evidence of disease) according to the 2007 IWG criteria, based on IRRC assessment.
Confidence interval based on Clopper-Pearson method.

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	80	100	
Units: Percentage of Participants				
number (confidence interval 95%)	31.7 (20.6 to 44.7)	13.8 (7.1 to 23.3)	21 (13.5 to 30.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Partial Remission (PR) Rate based on IRRC assessments in Cohorts A, B, and C

End point title	Partial Remission (PR) Rate based on IRRC assessments in Cohorts A, B, and C[8]

End point description:

The PR rate was defined as the percent of participants with a BOR of PR (regression of measurable disease and no new sites) according to the 2007 IWG criteria, based on IRRC assessment. Confidence interval based on Clopper-Pearson method.

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	80	100	
Units: Percentage of Participants				
number (confidence interval 95%)	33.3 (22.0 to 46.3)	57.5 (45.9 to 68.5)	54.0 (43.7 to 64.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Objective Response (DOR) based on investigator assessments in Cohorts A, B, and C

End point title	Duration of Objective Response (DOR) based on investigator assessments in Cohorts A, B, and C[9]

End point description:

DOR is the time from first response (complete remission (CR) or partial remission (PR)) to the date of initial objectively documented progression as determined using the 2007 IWG criteria or death due to any cause, whichever occurred first. For participants who neither progressed nor died, the DOR was censored on the date of their last tumor assessment. Participants who started subsequent therapy without a prior reported progression were censored at the last tumor assessments prior to initiation of the subsequent anticancer therapy.
CR is the percent of participants with a best overall response (BOR) of CR (disappearance of all evidence of disease) according to the 2007 IWG criteria, based on IRRC assessment.
PR is the percent of participants with a best overall response (BOR) of PR (regression of measurable disease and no new sites) according to the 2007 IWG criteria, based on IRRC assessment.
Computed using Kaplan-Meier method.
'99999'=NA

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	60	70	
Units: Months				
median (confidence interval 95%)	39.10 (16.59 to 78.29)	25.26 (10.09 to 41.72)	28.85 (12.02 to 34.53)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of PR based on IRRC assessments in Cohorts A, B, and C

End point title	Duration of PR based on IRRC assessments in Cohorts A, B, and C[10]

End point description:

The duration of PR was only evaluated in participants with BOR of PR and was defined as the time from first documentation of PR (regression of measurable disease and no new sites) to the date of initial objectively documented progression (any new lesion or increase by >=50% of previously involved sites from nadir) as determined using the 2007 IWG criteria or death due to any cause, whichever occurred first. Censoring was applied as per DOR definition.
Computed using Kaplan-Meier method.

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	46	54	
Units: Months				
median (confidence interval 95%)	12.78 (4.17 to 27.17)	10.58 (7.46 to 25.26)	14.65 (9.36 to 30.36)	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rates (ORR) based on Investigator assessments for Cohorts A, B, and C

End point title	Objective Response Rates (ORR) based on Investigator assessments for Cohorts A, B, and C[11]

End point description:

ORR is the percent of participants achieving either a complete remission (CR) or partial remission (PR) according to the 2007 IWG criteria. Analyses of efficacy endpoints were performed separately for each cohort, according to IWG 2007. For cohort A and B, if the bone marrow was involved by lymphoma before treatment, the infiltrate must have cleared on repeat bone marrow biopsy. For cohort C, no evidence of FDG-avid disease in bone marrow was required in all participants in lieu of bone marrow aspirate/ biopsy.
CR is the percent of participants with a best overall response (BOR) of CR (disappearance of all evidence of disease) according to the 2007 IWG criteria, based on IRRC assessment.
PR is the percent of participants with a best overall response (BOR) of PR (regression of measurable disease and no new sites) according to the 2007 IWG criteria, based on IRRC assessment.
Confidence interval based on Clopper-Pearson method.

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	80	100	
Units: Percentage of Participants				
number (confidence interval 95%)	69.8 (57.0 to 80.8)	75.0 (64.1 to 84.0)	70.0 (60.0 to 78.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Discontinuation Rate in Cohort D

End point title	Treatment Discontinuation Rate in Cohort D[12]

End point description:

Treatment discontinuation rate (TDR) is the number of treated participants who received <4 doses of monotherapy or <12 doses of their assigned combination regimen. A participant is considered as having received an AVD/NAVD dose as soon as they received at least one drug of AVD/NAVD for the considered dose. Participants must have received at least one dose of Nivolumab during the combination therapy phase to be included in participants treated with NAVD. If a participant subsequently met Criteria to Resume Nivolumab Dosing, the combination of nivolumab and AVD could be used. Participants who underwent treatment beyond progression during the Monotherapy phase could use the combination of nivolumab and AVD if all 4 doses of nivolumab monotherapy are completed.
Discontinuation can be due to any reason including, but not limited to, drug-related toxicity, diseases progression, or death.

End point type	Secondary

End point timeframe:

From first dose up until the date of treatment discontinuation (up to approximately 104 months).

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Monotherapy	2			
Combination Therapy (receiving AVD or NAVD)	5			
Combination Therapy (NAVD receivers only)	5			
Overall Therapy	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of Adverse Events (AEs) in Cohort D

End point title	Incidence of Adverse Events (AEs) in Cohort D[13]

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug. Toxicities were graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.0.

End point type	Secondary

End point timeframe:

From first dose of the considered therapy phase to 30 days after last dose of study therapy phase (or up to first dose of combination if any when considering the monotherapy period) (an average of 8 months and a maximum of 11 months)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Monotherapy	48			
Combination Therapy (receiving AVD or NAVD)	49			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who died in Cohort D

End point title	Number of participants who died in Cohort D[14]

End point description:

Number of participants who died in Cohort D within 100 days after last dose of study therapy.

End point type	Secondary

End point timeframe:

From first dose of the considered therapy phase to 100 days after last dose of study therapy phase (or up to first dose of combination if any when considering the monotherapy period) (an average of 10 months up to a maximum of 13 months)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Monotherapy	0			
Combination Therapy (receiving AVD or NAVD)	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of AEs Leading to Dose Delay in Cohort D

End point title	Incidence of AEs Leading to Dose Delay in Cohort D[15]

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug. Toxicities were graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.0.

End point type	Secondary

End point timeframe:

From first dose of the considered therapy phase to 30 days after last dose of study therapy phase (or up to first dose of combination if any when considering the monotherapy period) (an average of 8 months and a maximum of 11 months)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Monotherapy	3			
Combination Therapy (receiving AVD or NAVD)	29			

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of Serious Adverse Events (SAEs) in Cohort D

End point title	Incidence of Serious Adverse Events (SAEs) in Cohort D[16]

End point description:

A Serious Adverse Event (SAE) is any untoward medical occurrence that at any dose results in death, is life-threatening (defined as an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more

severe), requires inpatient hospitalization or causes prolongation of existing hospitalization. Toxicities were graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.0.

End point type	Secondary

End point timeframe:

From first dose of the considered therapy phase to 30 days after last dose of study therapy phase (or up to first dose of combination if any when considering the monotherapy period) (an average of 8 months and a maximum of 11 months)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Monotherapy	2			
Combination Therapy (receiving AVD or NAVD)	10			

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of AEs Leading to Discontinuation in Cohort D

End point title	Incidence of AEs Leading to Discontinuation in Cohort D[17]

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug. Toxicities were graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.0.

End point type	Secondary

End point timeframe:

From first dose of the considered therapy phase to 30 days after last dose of study therapy phase (or up to first dose of combination if any when considering the monotherapy period) (an average of 8 months and a maximum of 11 months)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Monotherapy	1			
Combination Therapy (receiving AVD or NAVD)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of Select AEs in Cohort D

End point title	Incidence of Select AEs in Cohort D[18]

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug. Toxicities were graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. Select AEs have been categorized into seven areas: pulmonary toxicity, gastrointestinal toxicity, hepatotoxicity, endocrinopathy, skin toxicity, neurological toxicity and renal toxicity. Select AEs, in particular pneumonitis, are considered clinically meaningful as they require greater vigilance and for early recognition and prompt intervention.

End point type	Secondary

End point timeframe:

From first dose of the considered therapy phase to 30 days after last dose of study therapy phase (or up to first dose of combination if any when considering the monotherapy period) (an average of 8 months and a maximum of 11 months)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
Gastrointestinal Monotherapy	6			
Gastrointestinal Combination Therapy	13			
Hepatic Monotherapy	2			
Hepatic Combination Therapy	3			
Pulmonary Monotherapy	0			
Pulmonary Combination Therapy	3			

Renal Monotherapy	1			
Renal Combination Therapy	0			
Skin Monotherapy	17			
Skin Combination Therapy	9			
Hypersensitivity/Infusion Reactions Monotherapy	16			
Hypersensitivity/Infusion Reactions Combination	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Laboratory Abnormalities in Specific Thyroid Tests in Cohort D Monotherapy Phase

End point title	Laboratory Abnormalities in Specific Thyroid Tests in Cohort D Monotherapy Phase[19]

End point description:

The number of participants with laboratory abnormalities in specific thyroid tests based on SI conventional units. TSH = Thyroid Stimulating Hormone LLN = Lower Limit of Normal ULN = Upper Limit of Normal

End point type	Secondary

End point timeframe:

From first dose of monotherapy to 30 days after last dose of monotherapy phase (up to approximately 3 months)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: Participants				
TSH > ULN	1			
TSH > ULN WITH TSH <= ULN AT BASELINE	1			
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0			
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	0			
TSH > ULN WITH FT3/FT4 TEST MISSING	1			
TSH < LLN	5			
TSH <LLN WITH TSH >= LLN AT BASELINE	5			
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	1			
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	0			

TSH < LLN WITH FT3/FT4 TEST MISSING	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Laboratory Abnormalities in Specific Thyroid Tests in Cohort D Combination Therapy Phase

End point title	Laboratory Abnormalities in Specific Thyroid Tests in Cohort D Combination Therapy Phase[20]

End point description:

The number of participants with laboratory abnormalities in specific thyroid tests based on SI conventional units. TSH = Thyroid Stimulating Hormone LLN = Lower Limit of Normal ULN = Upper Limit of Normal

End point type	Secondary

End point timeframe:

From first dose of the combination therapy to 30 days after last dose of combination therapy (an average of 8 months and a maximum of 11 months)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: Participants				
TSH > ULN	12			
TSH > ULN WITH TSH <= ULN AT BASELINE	8			
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	3			
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	1			
TSH > ULN WITH FT3/FT4 TEST MISSING	8			
TSH < LLN	5			
TSH <LLN WITH TSH >= LLN AT BASELINE	5			
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	1			
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	0			
TSH < LLN WITH FT3/FT4 TEST MISSING	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Laboratory Abnormalities in Specific Liver Tests in Cohort D Monotherapy Phase

End point title	Laboratory Abnormalities in Specific Liver Tests in Cohort D Monotherapy Phase[21]

End point description:

The number of participants with laboratory abnormalities in specific liver tests based on SI conventional units. ALT = Alanine Aminotransferase, AST = Aspartate Aminotransferase, ULN = Upper Limit of Normal.

End point type	Secondary

End point timeframe:

From first dose of monotherapy to 30 days after last dose of monotherapy phase (up to approximately 3 months)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Participants				
ALT OR AST > 3XULN	2			
ALT OR AST> 5XULN	1			
ALT OR AST> 10XULN	0			
ALT OR AST > 20XULN	0			
TOTAL BILIRUBIN > 2XULN	0			
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	0			
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN 30 DAYS	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Laboratory Abnormalities in Specific Liver Tests in Cohort D Combination Therapy Phase

End point title	Laboratory Abnormalities in Specific Liver Tests in Cohort D Combination Therapy Phase[22]

End point description:

The number of participants with laboratory abnormalities in specific liver tests based on SI conventional units. ALT = Alanine Aminotransferase, AST = Aspartate Aminotransferase, ULN = Upper Limit of Normal.

End point type	Secondary

End point timeframe:

From first dose of the combination therapy to 30 days after last dose of combination therapy (an average of 8 months and a maximum of 11 months)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	49			
Units: Participants				
ALT OR AST > 3XULN	4			
ALT OR AST> 5XULN	1			
ALT OR AST> 10XULN	1			
ALT OR AST > 20XULN	0			
TOTAL BILIRUBIN > 2XULN	0			
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	0			
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN 30 DAYS	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response (CR) Rate at planned end of therapy based on IRRC assessments in Cohort D

End point title	Complete Response (CR) Rate at planned end of therapy based on IRRC assessments in Cohort D[23]

End point description:

CR rate is the percent of participants who show CR (disappearance of all evidence of disease) according to the 2007 IWG criteria at the planned end of study therapy radiographic tumor assessment. Confidence interval based on the Klopper and Pearson method.

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, or death whichever occurred first (up to approximately 104 months)

Notes:

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

Justification: Analysis was only planned for Cohort D

End point values	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Percent of Participants				
number (confidence interval 95%)	66.7 (52.1 to 79.2)			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Post Hoc Analysis: Objective Response Rate (ORR) based on IRRC assessments in Cohorts A, B, and C Extended Collection

End point title	Post Hoc Analysis: Objective Response Rate (ORR) based on IRRC assessments in Cohorts A, B, and C Extended Collection[24]

End point description:

Represents an updated version of the primary endpoint to include additional data collection that occurred after the primary completion date. (Assessments were made until 30 Nov 2022). Clinical benefit of nivolumab, as measured by ORR per IRRC assessment, and defined as percent of participants achieving either complete remission (CR) or partial remission (PR) according to the 2007 IWG criteria. For cohort A and B, if the bone marrow was involved by lymphoma before treatment, the infiltrate must have cleared on repeat bone marrow biopsy. For cohort C, no evidence of FDG-avid disease in bone marrow was required in all patients in lieu of bone marrow aspirate/ biopsy. CR is the percent of participants with a best overall response (BOR) of CR (disappearance of all evidence of disease) according to the 2007 IWG criteria. PR is the percent of participants with a best overall response (BOR) of PR (regression of
measurable disease and no new sites) according to the 2007 IWG criteria.

End point type	Post-hoc

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, whichever occurred first (up to approximately 104 months)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Analysis was only planned for Cohorts A B and C

End point values	Cohort A: Post-Transplant, Never Taken Brentuximab Vedotin	Cohort B: Post Transplant Brentuximab Vedotin	Cohort C: Brentuximab Vedotin Pre- or Post Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	80	100	
Units: Percentage of Participants				
number (confidence interval 95%)	65.1 (52.0 to 76.7)	71.3 (60.0 to 80.8)	75.0 (65.3 to 83.1)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SAEs and Non-SAEs were assessed from first dose to 100 days after last dose of study therapy (assessed for an average of 32 months up to maximum of 98 months).

Adverse event reporting additional description:

Serious Adverse Events and Non-Serious Adverse Events represents all participants that received at least 1 dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Cohort A: Brentuximab Vedotin Naive-NIVO 240mg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression

Reporting group title	Cohort A: Brentuximab Vedotin Naive-NIVO 3mg/kg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort A: Brentuximab Vedotin Naive-NIVO 480mg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 240mg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 3mg/kg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort C: Brentuximab Vedotin Pre/Post Transplant-NIVO 3mg/kg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 480mg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort C: Brentuximab Vedotin Pre/Post Transplant-NIVO 240mg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort C: Brentuximab Vedotin Pre/Post Transplant-NIVO 480mg

Reporting group description:

Nivolumab was administered at 3 mg/kg IV over 60 minutes on the first day of each 2-week cycle. Upon the implementation of revised protocol version 04c (dated 22-Aug-2019), participants were switched from a body weight-based dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks. Nivolumab treatment was continued until unacceptable toxicity or disease progression.

Reporting group title	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL

Reporting group description:

Four doses of nivolumab flat dose 240 mg IV were administered every 2 weeks (monotherapy phase), followed by 12 doses of the combination of AVD (adriamycin/ doxorubicin 25 mg/m2, vinblastine 6 mg/m2, dacarbazine 375 mg/m2) chemotherapy and nivolumab flat dose 240 mg IV for 6 cycles (combination phase).

Serious adverse events	Cohort A: Brentuximab Vedotin Naive-NIVO 240mg	Cohort A: Brentuximab Vedotin Naive-NIVO 3mg/kg	Cohort A: Brentuximab Vedotin Naive-NIVO 480mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 9 (33.33%)	10 / 46 (21.74%)	1 / 8 (12.50%)
number of deaths (all causes)	3	14	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Breast cancer			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular lymphoma stage III			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 T-cell lymphoma unspecified			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (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
Generalised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute graft versus host disease			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (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
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheomalacia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respirovirus test positive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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 compression fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (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
Palpitations			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (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
Myocardial infarction			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
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 disorders			
Polyneuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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			

Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Pancreatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteonecrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue disorder			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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

Polyarthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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			
Atypical pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (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
Bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 sepsis			

subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Erysipelas			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lyme disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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 respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (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
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucose tolerance impaired			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
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 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 240mg	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 3mg/kg	Cohort C: Brentuximab Vedotin Pre/Post Transplant-NIVO 3mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	30 / 75 (40.00%)	33 / 84 (39.29%)
number of deaths (all causes)	0	25	31
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Malignant neoplasm progression			

subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	4 / 84 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 4
Breast cancer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Follicular lymphoma stage III			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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 T-cell lymphoma unspecified			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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			
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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 ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	3 / 84 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
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 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Graft versus host disease			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute graft versus host disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	2 / 84 (2.38%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	3 / 84 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheomalacia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
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 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respirovirus test positive			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	2 / 84 (2.38%)
occurrences causally related to treatment / all	0 / 0	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Muscle rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (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
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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 failure congestive			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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			
Polyneuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	2 / 84 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	1 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	2 / 84 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteonecrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Polyarthritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (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 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Device related sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	2 / 84 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lyme disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (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
Respiratory tract infection			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
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			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	5 / 84 (5.95%)
occurrences causally related to treatment / all	0 / 0	0 / 5	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (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 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (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
Appendicitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Bacterial sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
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 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucose tolerance impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (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
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 480mg	Cohort C: Brentuximab Vedotin Pre/Post Transplant-NIVO 240mg	Cohort C: Brentuximab Vedotin Pre/Post Transplant-NIVO 480mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	8 / 13 (61.54%)	3 / 3 (100.00%)
number of deaths (all causes)	0	4	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular lymphoma stage III			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 T-cell lymphoma unspecified			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Graft versus host disease			

subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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
Acute graft versus host disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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
Tracheomalacia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respirovirus test positive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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			
Acute myocardial infarction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Polyneuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteonecrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Polyarthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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			
Atypical pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 sepsis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lyme disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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
Appendicitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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
Glucose tolerance impaired			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (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
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 51 (23.53%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Follicular lymphoma stage III				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal cell carcinoma				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma of the skin				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral T-cell lymphoma unspecified				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the tongue				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Embolism				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Peripheral ischaemia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Pregnancy				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Pyrexia				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Graft versus host disease				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute graft versus host disease			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Acute respiratory failure				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Haemoptysis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheomalacia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Suicide attempt				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Alanine aminotransferase increased				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipase increased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respirovirus test positive				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Infusion related reaction				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle rupture				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Tracheo-oesophageal fistula				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute myocardial infarction				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Pericardial effusion				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Polyneuropathy			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			

Febrile neutropenia				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	1 / 1			
Anaemia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Colitis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated enterocolitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Autoimmune hepatitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Rash maculo-papular				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pruritus				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tubulointerstitial nephritis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Hyperthyroidism				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Osteonecrosis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue disorder				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Polyarthritis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Atypical pneumonia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lyme disease				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				

subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Pyelonephritis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis A				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				

subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glucose tolerance impaired				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Cohort A: Brentuximab Vedotin Naive-NIVO 240mg	Cohort A: Brentuximab Vedotin Naive-NIVO 3mg/kg	Cohort A: Brentuximab Vedotin Naive-NIVO 480mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	46 / 46 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Tumour pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			

Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Flushing			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Lymphoedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Peripheral venous disease			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Superficial vein thrombosis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	3 / 8 (37.50%)
occurrences (all)	0	2	4
Mucosal inflammation			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	0 / 8 (0.00%)
occurrences (all)	1	5	0
Fatigue			
subjects affected / exposed	5 / 9 (55.56%)	19 / 46 (41.30%)	3 / 8 (37.50%)
occurrences (all)	6	39	9
Chills			
subjects affected / exposed	3 / 9 (33.33%)	2 / 46 (4.35%)	1 / 8 (12.50%)
occurrences (all)	3	4	1
Chest pain			

subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	3	5	0
Asthenia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	2 / 8 (25.00%)
occurrences (all)	1	5	3
Pyrexia			
subjects affected / exposed	5 / 9 (55.56%)	12 / 46 (26.09%)	3 / 8 (37.50%)
occurrences (all)	7	20	6
Pain			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Chest discomfort			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Feeling cold			
subjects affected / exposed	2 / 9 (22.22%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Illness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	2 / 9 (22.22%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Mucosal dryness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	5
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Thirst			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	2 / 8 (25.00%)
occurrences (all)	1	2	2
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Cytokine release syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anaphylactic reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Menopausal symptoms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Balanoposthitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	3 / 9 (33.33%)	6 / 46 (13.04%)	2 / 8 (25.00%)
occurrences (all)	3	9	8
Cough			
subjects affected / exposed	5 / 9 (55.56%)	21 / 46 (45.65%)	4 / 8 (50.00%)
occurrences (all)	9	34	16
Dyspnoea			
subjects affected / exposed	2 / 9 (22.22%)	4 / 46 (8.70%)	1 / 8 (12.50%)
occurrences (all)	2	6	1
Nasal congestion			

subjects affected / exposed	0 / 9 (0.00%)	9 / 46 (19.57%)	5 / 8 (62.50%)
occurrences (all)	0	16	18
Productive cough			
subjects affected / exposed	2 / 9 (22.22%)	4 / 46 (8.70%)	3 / 8 (37.50%)
occurrences (all)	6	15	8
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	3 / 8 (37.50%)
occurrences (all)	0	4	3
Wheezing			
subjects affected / exposed	2 / 9 (22.22%)	2 / 46 (4.35%)	1 / 8 (12.50%)
occurrences (all)	2	2	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dry throat			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Increased viscosity of upper respiratory secretion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Dysphonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	3
Pneumonitis			

subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	1 / 8 (12.50%)
occurrences (all)	0	3	2
Paranasal sinus inflammation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Painful respiration			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	2 / 8 (25.00%)
occurrences (all)	0	2	3
Upper-airway cough syndrome			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	2 / 8 (25.00%)
occurrences (all)	0	2	5
Sinus congestion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Depression			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	1 / 8 (12.50%)
occurrences (all)	1	4	14
Anxiety disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Depressed mood			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Generalised anxiety disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase increased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	6 / 46 (13.04%)	2 / 8 (25.00%)
occurrences (all)	2	9	4
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	2 / 8 (25.00%)
occurrences (all)	1	7	4
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	1	3	0
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Lipase increased			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	1 / 8 (12.50%)
occurrences (all)	3	5	1
Weight increased			
subjects affected / exposed	1 / 9 (11.11%)	3 / 46 (6.52%)	1 / 8 (12.50%)
occurrences (all)	1	4	1
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	8
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	5 / 46 (10.87%)	0 / 8 (0.00%)
occurrences (all)	0	7	0
Weight decreased			

subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	3 / 8 (37.50%)
occurrences (all)	0	3	3
Lymphocyte count decreased			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	1 / 8 (12.50%)
occurrences (all)	0	9	2
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sputum abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	6 / 46 (13.04%)	0 / 8 (0.00%)
occurrences (all)	0	7	0
Arthropod bite			

subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Ankle fracture			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Skin procedural complication			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Compression fracture			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Fall			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Ligament sprain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Pelvic fracture			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cardiac disorders			

Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	1 / 8 (12.50%)
occurrences (all)	0	3	1
Nervous system disorders			
Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	6 / 46 (13.04%)	1 / 8 (12.50%)
occurrences (all)	0	6	1
Headache			
subjects affected / exposed	3 / 9 (33.33%)	14 / 46 (30.43%)	2 / 8 (25.00%)
occurrences (all)	5	24	6
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 9 (11.11%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	1	4	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	2
Dysaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Convulsions local			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	3	1	1
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Migraine with aura			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	1 / 8 (12.50%)
occurrences (all)	1	9	2
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Neutropenia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	0 / 8 (0.00%)
occurrences (all)	1	7	0
Leukopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2

Eosinophilia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	5
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Vertigo			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Tinnitus			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 9 (11.11%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	1	3	0
Visual field defect			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Mydriasis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 9 (33.33%)	26 / 46 (56.52%)	5 / 8 (62.50%)
occurrences (all)	7	46	6
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Constipation			
subjects affected / exposed	2 / 9 (22.22%)	7 / 46 (15.22%)	1 / 8 (12.50%)
occurrences (all)	2	7	1
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	7 / 46 (15.22%)	0 / 8 (0.00%)
occurrences (all)	1	8	0
Abdominal pain upper			
subjects affected / exposed	3 / 9 (33.33%)	6 / 46 (13.04%)	0 / 8 (0.00%)
occurrences (all)	3	7	0
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 9 (11.11%)	14 / 46 (30.43%)	5 / 8 (62.50%)
occurrences (all)	1	26	11
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	5 / 46 (10.87%)	1 / 8 (12.50%)
occurrences (all)	0	7	1
Toothache			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	1 / 8 (12.50%)
occurrences (all)	1	2	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	4 / 46 (8.70%)	1 / 8 (12.50%)
occurrences (all)	0	5	1
Vomiting			
subjects affected / exposed	2 / 9 (22.22%)	11 / 46 (23.91%)	5 / 8 (62.50%)
occurrences (all)	3	23	6
Abdominal discomfort			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Abdominal hernia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pancreatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Steatorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	5	0
Hepatobiliary disorders			
Hepatic steatosis			

subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Venoocclusive liver disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 9 (33.33%)	11 / 46 (23.91%)	1 / 8 (12.50%)
occurrences (all)	5	15	1
Dry skin			
subjects affected / exposed	1 / 9 (11.11%)	5 / 46 (10.87%)	1 / 8 (12.50%)
occurrences (all)	1	5	1
Hyperhidrosis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Night sweats			
subjects affected / exposed	3 / 9 (33.33%)	3 / 46 (6.52%)	1 / 8 (12.50%)
occurrences (all)	4	4	1
Alopecia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	4 / 8 (50.00%)
occurrences (all)	0	3	7
Rash			
subjects affected / exposed	0 / 9 (0.00%)	12 / 46 (26.09%)	2 / 8 (25.00%)
occurrences (all)	0	21	3
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	5 / 46 (10.87%)	0 / 8 (0.00%)
occurrences (all)	0	5	0
Acne			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	1

Dermatitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	1	2	1
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Cystitis haemorrhagic			

subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Urinary tract pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	1 / 9 (11.11%)	7 / 46 (15.22%)	1 / 8 (12.50%)
occurrences (all)	1	8	1
Primary hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 9 (11.11%)	8 / 46 (17.39%)	2 / 8 (25.00%)
occurrences (all)	1	9	2
Arthralgia			
subjects affected / exposed	4 / 9 (44.44%)	9 / 46 (19.57%)	2 / 8 (25.00%)
occurrences (all)	6	12	2
Bone pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	1 / 8 (12.50%)
occurrences (all)	0	4	1
Myalgia			
subjects affected / exposed	1 / 9 (11.11%)	7 / 46 (15.22%)	2 / 8 (25.00%)
occurrences (all)	1	11	2
Pain in extremity			
subjects affected / exposed	1 / 9 (11.11%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	1	3	0
Flank pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	2 / 9 (22.22%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	3	1	0
Joint effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Muscle contracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Muscle swelling			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Osteoporosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Plantar fasciitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	2 / 9 (22.22%)	2 / 46 (4.35%)	3 / 8 (37.50%)
occurrences (all)	4	2	3
Sinusitis			
subjects affected / exposed	3 / 9 (33.33%)	2 / 46 (4.35%)	1 / 8 (12.50%)
occurrences (all)	3	2	1
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 46 (8.70%)	1 / 8 (12.50%)
occurrences (all)	1	6	1
Respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	3 / 9 (33.33%)	1 / 46 (2.17%)	1 / 8 (12.50%)
occurrences (all)	3	1	7
Gastrointestinal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	11 / 46 (23.91%)	3 / 8 (37.50%)
occurrences (all)	1	17	11
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	1 / 8 (12.50%)
occurrences (all)	0	3	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	2 / 8 (25.00%)
occurrences (all)	0	1	2

Atypical mycobacterial infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aeromonas infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Bacterial infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 9 (11.11%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Folliculitis			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Gastric infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Lymph gland infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Lip infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	3 / 9 (33.33%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	3	2	0
Infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Infected skin ulcer			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 9 (55.56%)	10 / 46 (21.74%)	6 / 8 (75.00%)
occurrences (all)	6	22	15
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	4 / 46 (8.70%)	2 / 8 (25.00%)
occurrences (all)	0	4	2
Tooth infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Tooth abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Septic shock			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 9 (33.33%)	5 / 46 (10.87%)	2 / 8 (25.00%)
occurrences (all)	3	10	2
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	6	0
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 46 (6.52%)	0 / 8 (0.00%)
occurrences (all)	0	7	0
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Non-serious adverse events	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 240mg	Cohort B: Post Transplant Brentuximab Vedotin-NIVO 3mg/kg	Cohort C: Brentuximab Vedotin Pre/Post Transplant-NIVO 3mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	75 / 75 (100.00%)	80 / 84 (95.24%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	5 / 75 (6.67%)	2 / 84 (2.38%)
occurrences (all)	1	6	2
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	4 / 84 (4.76%)
occurrences (all)	0	2	5
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Peripheral venous disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	11 / 84 (13.10%)
occurrences (all)	0	8	11
Influenza like illness			
subjects affected / exposed	2 / 3 (66.67%)	5 / 75 (6.67%)	2 / 84 (2.38%)
occurrences (all)	4	5	2
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	2 / 84 (2.38%)
occurrences (all)	0	6	2
Fatigue			

subjects affected / exposed	1 / 3 (33.33%)	36 / 75 (48.00%)	27 / 84 (32.14%)
occurrences (all)	1	58	44
Chills			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	4 / 84 (4.76%)
occurrences (all)	0	4	4
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	3 / 84 (3.57%)
occurrences (all)	0	0	3
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	9 / 75 (12.00%)	3 / 84 (3.57%)
occurrences (all)	0	10	3
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	33 / 75 (44.00%)	29 / 84 (34.52%)
occurrences (all)	1	53	40
Pain			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	4 / 84 (4.76%)
occurrences (all)	0	6	4
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	3 / 84 (3.57%)
occurrences (all)	0	1	3
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Illness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	3 / 84 (3.57%)
occurrences (all)	0	4	3
Mucosal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	2 / 84 (2.38%)
occurrences (all)	0	1	3
Peripheral swelling			
subjects affected / exposed	1 / 3 (33.33%)	4 / 75 (5.33%)	3 / 84 (3.57%)
occurrences (all)	1	6	3
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	3	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	4	0
Cytokine release syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	7	0	0
Anaphylactic reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Menopausal symptoms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Balanoposthitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	14 / 75 (18.67%)	11 / 84 (13.10%)
occurrences (all)	1	20	11
Cough			

subjects affected / exposed	0 / 3 (0.00%)	31 / 75 (41.33%)	28 / 84 (33.33%)
occurrences (all)	0	66	44
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	14 / 75 (18.67%)	13 / 84 (15.48%)
occurrences (all)	0	23	18
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	9 / 75 (12.00%)	8 / 84 (9.52%)
occurrences (all)	0	13	8
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	4 / 84 (4.76%)
occurrences (all)	0	10	7
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	8 / 84 (9.52%)
occurrences (all)	0	5	11
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	4 / 84 (4.76%)
occurrences (all)	0	4	5
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	1 / 84 (1.19%)
occurrences (all)	0	3	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Increased viscosity of upper respiratory secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	3 / 84 (3.57%)
occurrences (all)	0	3	5
Dyspnoea exertional			

subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	3 / 84 (3.57%)
occurrences (all)	0	5	4
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	2 / 84 (2.38%)
occurrences (all)	0	1	2
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	4 / 84 (4.76%)
occurrences (all)	0	8	6
Paranasal sinus inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Painful respiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Respiratory tract congestion			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	4 / 84 (4.76%)
occurrences (all)	0	10	5
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	0	2
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	2 / 84 (2.38%)
occurrences (all)	0	3	2
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	2 / 84 (2.38%)
occurrences (all)	0	5	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	5 / 84 (5.95%)
occurrences (all)	0	6	5
Depression			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	4 / 84 (4.76%)
occurrences (all)	0	5	4

Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	12 / 75 (16.00%)	7 / 84 (8.33%)
occurrences (all)	0	14	7
Anxiety disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Generalised anxiety disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	3 / 84 (3.57%)
occurrences (all)	0	8	5
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	11 / 75 (14.67%)	9 / 84 (10.71%)
occurrences (all)	0	16	18
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	9 / 75 (12.00%)	10 / 84 (11.90%)
occurrences (all)	0	15	17
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	8 / 84 (9.52%)
occurrences (all)	0	11	10
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	3 / 84 (3.57%)
occurrences (all)	0	16	4
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	16 / 75 (21.33%)	4 / 84 (4.76%)
occurrences (all)	0	22	8
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	8 / 84 (9.52%)
occurrences (all)	0	16	9
Neutrophil count decreased			

subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	0 / 84 (0.00%)
occurrences (all)	0	14	0
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 75 (1.33%)	3 / 84 (3.57%)
occurrences (all)	1	1	4
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	4 / 84 (4.76%)
occurrences (all)	0	7	4
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	5 / 84 (5.95%)
occurrences (all)	0	12	13
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	3 / 84 (3.57%)
occurrences (all)	0	13	3
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	2
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	2 / 84 (2.38%)
occurrences (all)	0	3	2
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	2 / 84 (2.38%)
occurrences (all)	0	5	2
Sputum abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	13 / 75 (17.33%)	9 / 84 (10.71%)
occurrences (all)	1	16	10
Arthropod bite			
subjects affected / exposed	1 / 3 (33.33%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	1	2	0
Ankle fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Skin procedural complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Pelvic fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			

subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	2 / 84 (2.38%)
occurrences (all)	0	1	2
Wrist fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	1 / 84 (1.19%)
occurrences (all)	0	7	1
Palpitations			
subjects affected / exposed	1 / 3 (33.33%)	1 / 75 (1.33%)	3 / 84 (3.57%)
occurrences (all)	1	1	4
Nervous system disorders			
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	3 / 84 (3.57%)
occurrences (all)	0	2	3
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	10 / 75 (13.33%)	7 / 84 (8.33%)
occurrences (all)	1	15	12
Headache			
subjects affected / exposed	0 / 3 (0.00%)	15 / 75 (20.00%)	13 / 84 (15.48%)
occurrences (all)	0	26	17
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	1 / 84 (1.19%)
occurrences (all)	0	6	1
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	9 / 75 (12.00%)	3 / 84 (3.57%)
occurrences (all)	0	12	3
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	2 / 84 (2.38%)
occurrences (all)	0	3	2
Cerebrospinal fluid leakage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	2 / 84 (2.38%)
occurrences (all)	0	1	2
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Convulsions local			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 84 (0.00%)
occurrences (all)	0	3	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	0	3	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Polyneuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	12 / 75 (16.00%)	18 / 84 (21.43%)
occurrences (all)	0	16	26
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1

Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	14 / 84 (16.67%)
occurrences (all)	0	9	16
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	9 / 84 (10.71%)
occurrences (all)	0	9	23
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 84 (0.00%)
occurrences (all)	0	4	0
Eosinophilia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	1 / 84 (1.19%)
occurrences (all)	0	4	1
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences (all)	0	2	1
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	2 / 84 (2.38%)
occurrences (all)	0	4	2
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 3 (33.33%)	3 / 75 (4.00%)	7 / 84 (8.33%)
occurrences (all)	1	5	9
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	4 / 84 (4.76%)
occurrences (all)	0	1	6
Visual field defect			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Swelling of eyelid			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Eye disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences (all)	0	7	1
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
Mydriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	37 / 75 (49.33%)	25 / 84 (29.76%)
occurrences (all)	1	73	38
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	4 / 84 (4.76%)
occurrences (all)	0	3	4
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	14 / 75 (18.67%)	15 / 84 (17.86%)
occurrences (all)	1	20	19
Abdominal pain			
subjects affected / exposed	2 / 3 (66.67%)	14 / 75 (18.67%)	13 / 84 (15.48%)
occurrences (all)	3	20	15
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	3 / 84 (3.57%)
occurrences (all)	0	3	4
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	20 / 75 (26.67%)	19 / 84 (22.62%)
occurrences (all)	1	35	32
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	4 / 84 (4.76%)
occurrences (all)	0	8	8

Toothache			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	2 / 84 (2.38%)
occurrences (all)	0	7	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	4 / 84 (4.76%)
occurrences (all)	0	8	4
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	1 / 84 (1.19%)
occurrences (all)	0	5	1
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	5 / 84 (5.95%)
occurrences (all)	0	5	5
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	18 / 75 (24.00%)	19 / 84 (22.62%)
occurrences (all)	0	34	24
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	0 / 84 (0.00%)
occurrences (all)	0	4	0
Abdominal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 3 (33.33%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	1	2	0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Periodontal disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

Steatorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	1 / 84 (1.19%)
occurrences (all)	0	2	1
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Venoocclusive liver disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	22 / 75 (29.33%)	14 / 84 (16.67%)
occurrences (all)	1	33	19
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	4 / 84 (4.76%)
occurrences (all)	0	1	4
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	4 / 84 (4.76%)
occurrences (all)	0	6	4
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	5 / 84 (5.95%)
occurrences (all)	0	7	5
Rash			
subjects affected / exposed	1 / 3 (33.33%)	21 / 75 (28.00%)	13 / 84 (15.48%)
occurrences (all)	1	29	19
Rash maculo-papular			
subjects affected / exposed	1 / 3 (33.33%)	4 / 75 (5.33%)	1 / 84 (1.19%)
occurrences (all)	1	4	1
Acne			

subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Pityriasis rosea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	1 / 84 (1.19%)
occurrences (all)	0	2	1
Dermatitis allergic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Rash vesicular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	2 / 3 (66.67%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	3	0	1
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	3 / 84 (3.57%)
occurrences (all)	0	4	3
Renal and urinary disorders			

Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	3 / 84 (3.57%)
occurrences (all)	0	4	3
Cystitis haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	3 / 84 (3.57%)
occurrences (all)	0	2	3
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	9 / 75 (12.00%)	7 / 84 (8.33%)
occurrences (all)	0	12	7
Primary hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	1 / 84 (1.19%)
occurrences (all)	0	5	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	17 / 75 (22.67%)	12 / 84 (14.29%)
occurrences (all)	1	21	19
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	27 / 75 (36.00%)	15 / 84 (17.86%)
occurrences (all)	1	35	21
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	3 / 84 (3.57%)
occurrences (all)	0	2	4
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	11 / 75 (14.67%)	5 / 84 (5.95%)
occurrences (all)	0	11	9
Myalgia			

subjects affected / exposed	1 / 3 (33.33%)	11 / 75 (14.67%)	9 / 84 (10.71%)
occurrences (all)	1	16	19
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	7 / 84 (8.33%)
occurrences (all)	0	9	8
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Joint effusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	1	0	1
Joint swelling			
subjects affected / exposed	1 / 3 (33.33%)	4 / 75 (5.33%)	1 / 84 (1.19%)
occurrences (all)	1	4	1
Muscle contracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Muscle swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	4 / 84 (4.76%)
occurrences (all)	0	2	4
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	1 / 84 (1.19%)
occurrences (all)	0	2	1
Osteoporosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Spinal pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	2 / 84 (2.38%)
occurrences (all)	0	7	2
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	4 / 84 (4.76%)
occurrences (all)	0	7	5
Pneumonia			
subjects affected / exposed	2 / 3 (66.67%)	13 / 75 (17.33%)	6 / 84 (7.14%)
occurrences (all)	2	23	7
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	1 / 84 (1.19%)
occurrences (all)	0	6	1
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	3 / 84 (3.57%)
occurrences (all)	0	10	3
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	0 / 84 (0.00%)
occurrences (all)	0	6	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	1 / 84 (1.19%)
occurrences (all)	0	7	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	28 / 75 (37.33%)	18 / 84 (21.43%)
occurrences (all)	1	62	26
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	7 / 75 (9.33%)	3 / 84 (3.57%)
occurrences (all)	0	18	4
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

Viral infection			
subjects affected / exposed	2 / 3 (66.67%)	5 / 75 (6.67%)	0 / 84 (0.00%)
occurrences (all)	3	6	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Atypical mycobacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Aeromonas infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 3 (33.33%)	3 / 75 (4.00%)	1 / 84 (1.19%)
occurrences (all)	1	4	1
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	1 / 84 (1.19%)
occurrences (all)	0	6	1
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 75 (5.33%)	3 / 84 (3.57%)
occurrences (all)	0	5	5
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	0	3
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	1 / 84 (1.19%)
occurrences (all)	0	4	1
Gastric infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

Herpes simplex			
subjects affected / exposed	1 / 3 (33.33%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
Lymph gland infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Lip infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	5 / 84 (5.95%)
occurrences (all)	0	5	5
Infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Infected skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 3 (100.00%)	21 / 75 (28.00%)	10 / 84 (11.90%)
occurrences (all)	16	51	23
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	3 / 84 (3.57%)
occurrences (all)	0	2	3
Tooth infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	1 / 3 (33.33%)	0 / 75 (0.00%)	1 / 84 (1.19%)
occurrences (all)	1	0	1
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 75 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	3 / 84 (3.57%)
occurrences (all)	0	1	3
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	3 / 75 (4.00%)	3 / 84 (3.57%)
occurrences (all)	0	4	3
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	11 / 75 (14.67%)	7 / 84 (8.33%)
occurrences (all)	0	15	7
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	8 / 75 (10.67%)	7 / 84 (8.33%)
occurrences (all)	0	20	14
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 75 (6.67%)	4 / 84 (4.76%)
occurrences (all)	0	6	4
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 75 (2.67%)	6 / 84 (7.14%)
occurrences (all)	0	6	10
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 75 (8.00%)	4 / 84 (4.76%)
occurrences (all)	0	11	8
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	3 / 84 (3.57%)
occurrences (all)	0	2	3
Vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 75 (1.33%)	0 / 84 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Cohort B: Post Transplant Brentuximab	Cohort C: Brentuximab Vedotin Pre/Post Transplant-	Cohort C: Brentuximab Vedotin Pre/Post

	Vedotin-NIVO 480mg	NIVO 240mg	Transplant-NIVO 480mg
Total subjects affected by non-serious adverse events subjects affected / exposed	2 / 2 (100.00%)	13 / 13 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tumour pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	0	1	3
Lymphoedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral venous disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	2 / 3 (66.67%)
occurrences (all)	1	1	4

Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Fatigue			
subjects affected / exposed	2 / 2 (100.00%)	2 / 13 (15.38%)	2 / 3 (66.67%)
occurrences (all)	3	3	3
Chills			
subjects affected / exposed	0 / 2 (0.00%)	3 / 13 (23.08%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	2 / 2 (100.00%)	2 / 13 (15.38%)	1 / 3 (33.33%)
occurrences (all)	3	2	2
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Mucosal dryness			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cytokine release syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaphylactic reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Menopausal symptoms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Oropharyngeal pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Cough			
subjects affected / exposed	1 / 2 (50.00%)	5 / 13 (38.46%)	2 / 3 (66.67%)
occurrences (all)	3	9	9
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	3 / 13 (23.08%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Nasal congestion			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	1	1	2
Productive cough			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Increased viscosity of upper respiratory secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			

subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Painful respiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1

Depression			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
Insomnia			
subjects affected / exposed	2 / 2 (100.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Anxiety disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Investigations			
Amylase increased			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Weight increased			

subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	2 / 13 (15.38%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Blood bilirubin increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sputum abnormal			

subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Arthropod bite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin procedural complication			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Compression fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pelvic fracture			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Wrist fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	3 / 13 (23.08%)	2 / 3 (66.67%)
occurrences (all)	0	3	6
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Peripheral sensory neuropathy			

subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Convulsions local			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Post herpetic neuralgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Polyneuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 13 (15.38%)	0 / 3 (0.00%)
occurrences (all)	0	2	0

Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 13 (15.38%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	7
Visual field defect			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eye disorder			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mydriasis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 2 (100.00%)	6 / 13 (46.15%)	1 / 3 (33.33%)
occurrences (all)	2	8	1
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	7
Abdominal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	1	1	4

Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	1	2	3
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal hernia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Periodontal disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Steatorrhoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Venoocclusive liver disease			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 2 (50.00%)	3 / 13 (23.08%)	1 / 3 (33.33%)
occurrences (all)	2	3	2
Dry skin			
subjects affected / exposed	1 / 2 (50.00%)	3 / 13 (23.08%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	5
Rash			
subjects affected / exposed	0 / 2 (0.00%)	2 / 13 (15.38%)	1 / 3 (33.33%)
occurrences (all)	0	4	1
Rash maculo-papular			

subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Acne			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pityriasis rosea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Skin exfoliation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash vesicular			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	2 / 13 (15.38%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Primary hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Arthralgia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	2	2	1
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Muscle spasms			

subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Osteoporosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Periarthritis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Plantar fasciitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Sinusitis			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	1	4	1
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	3 / 13 (23.08%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	1 / 3 (33.33%)
occurrences (all)	0	1	1

Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	2 / 13 (15.38%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Viral infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Atypical mycobacterial infection			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Aeromonas infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastric infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Gingivitis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymph gland infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 2 (50.00%)	3 / 13 (23.08%)	2 / 3 (66.67%)
occurrences (all)	1	11	7
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	2 / 13 (15.38%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Septic shock			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pyelonephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pharyngitis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	2 / 3 (66.67%)
occurrences (all)	0	1	4
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 13 (7.69%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vitamin B12 deficiency			

subjects affected / exposed	0 / 2 (0.00%)	0 / 13 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort D: Newly Diagnosed, Previously Untreated Advanced cHL		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 51 (98.04%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Tumour pain			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	2		
Flushing			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Lymphoedema			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Peripheral venous disease			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Superficial vein thrombosis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			

Oedema peripheral				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	5			
Influenza like illness				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Mucosal inflammation				
subjects affected / exposed	5 / 51 (9.80%)			
occurrences (all)	8			
Fatigue				
subjects affected / exposed	19 / 51 (37.25%)			
occurrences (all)	43			
Chills				
subjects affected / exposed	6 / 51 (11.76%)			
occurrences (all)	7			
Chest pain				
subjects affected / exposed	4 / 51 (7.84%)			
occurrences (all)	6			
Asthenia				
subjects affected / exposed	7 / 51 (13.73%)			
occurrences (all)	8			
Pyrexia				
subjects affected / exposed	20 / 51 (39.22%)			
occurrences (all)	32			
Pain				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences (all)	3			
Chest discomfort				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	2			
Feeling cold				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Illness				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

Inflammation subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Malaise subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1		
Mucosal dryness subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Non-cardiac chest pain subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1		
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Thirst subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	2 / 51 (3.92%) 2		
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Cytokine release syndrome subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Anaphylactic reaction subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Reproductive system and breast disorders Amenorrhoea subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Menopausal symptoms			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Balanoposthitis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	2		
Cough			
subjects affected / exposed	13 / 51 (25.49%)		
occurrences (all)	15		
Dyspnoea			
subjects affected / exposed	6 / 51 (11.76%)		
occurrences (all)	10		
Nasal congestion			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	4		
Productive cough			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	2		
Rhinorrhoea			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	3		
Wheezing			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Dry throat			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Increased viscosity of upper respiratory secretion				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Haemoptysis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Dyspnoea exertional				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	3			
Dysphonia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Pneumonitis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Paranasal sinus inflammation				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Painful respiration				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Respiratory tract congestion				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Sinus pain				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Sneezing				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Upper-airway cough syndrome				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			

Sinus congestion subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 3		
Depression subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1		
Insomnia subjects affected / exposed occurrences (all)	5 / 51 (9.80%) 5		
Anxiety disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Depressed mood subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Generalised anxiety disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Investigations Amylase increased subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 3		
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 4		
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	2 / 51 (3.92%) 2		
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Blood creatinine increased			

subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Lipase increased				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	3			
Weight increased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Neutrophil count decreased				
subjects affected / exposed	10 / 51 (19.61%)			
occurrences (all)	21			
Platelet count decreased				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Weight decreased				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Lymphocyte count decreased				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences (all)	4			
White blood cell count decreased				
subjects affected / exposed	9 / 51 (17.65%)			
occurrences (all)	13			
SARS-CoV-2 test positive				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Liver function test increased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Blood thyroid stimulating hormone increased				

subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Blood bilirubin increased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Sputum abnormal				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Transaminases increased				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Injury, poisoning and procedural complications				
Infusion related reaction				
subjects affected / exposed	16 / 51 (31.37%)			
occurrences (all)	19			
Arthropod bite				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Ankle fracture				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Skin procedural complication				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Skin laceration				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Compression fracture				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Contusion				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Fall				

subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Ligament sprain			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Pelvic fracture			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Post-traumatic pain			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Sunburn			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Wrist fracture			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Palpitations			
subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	2		
Nervous system disorders			
Memory impairment			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	4		
Dizziness			
subjects affected / exposed	8 / 51 (15.69%)		
occurrences (all)	14		
Headache			
subjects affected / exposed	7 / 51 (13.73%)		
occurrences (all)	10		
Hypoaesthesia			

subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Neuropathy peripheral				
subjects affected / exposed	5 / 51 (9.80%)			
occurrences (all)	5			
Peripheral sensory neuropathy				
subjects affected / exposed	4 / 51 (7.84%)			
occurrences (all)	5			
Cerebrospinal fluid leakage				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Lethargy				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Dysaesthesia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Convulsions local				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Migraine				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Syncope				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Post herpetic neuralgia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Polyneuropathy				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences (all)	4			
Migraine with aura				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Tremor				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 51 (17.65%)		
occurrences (all)	10		
Febrile neutropenia			
subjects affected / exposed	4 / 51 (7.84%)		
occurrences (all)	5		
Thrombocytopenia			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	28 / 51 (54.90%)		
occurrences (all)	48		
Leukopenia			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Eosinophilia			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	3		
Tinnitus			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Vision blurred			

subjects affected / exposed	4 / 51 (7.84%)		
occurrences (all)	4		
Visual field defect			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Vitreous floaters			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Swelling of eyelid			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Eye disorder			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Eye pruritus			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Mydriasis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	17 / 51 (33.33%)		
occurrences (all)	32		
Dry mouth			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	3		
Constipation			
subjects affected / exposed	18 / 51 (35.29%)		
occurrences (all)	26		
Abdominal pain			
subjects affected / exposed	4 / 51 (7.84%)		
occurrences (all)	4		
Abdominal pain upper			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		

Haemorrhoids				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences (all)	3			
Nausea				
subjects affected / exposed	31 / 51 (60.78%)			
occurrences (all)	61			
Stomatitis				
subjects affected / exposed	12 / 51 (23.53%)			
occurrences (all)	16			
Toothache				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences (all)	3			
Gastrooesophageal reflux disease				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	3			
Dysphagia				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	4 / 51 (7.84%)			
occurrences (all)	4			
Vomiting				
subjects affected / exposed	15 / 51 (29.41%)			
occurrences (all)	21			
Abdominal discomfort				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	2			
Abdominal distension				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Abdominal hernia				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Anorectal discomfort				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

Flatulence subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1		
Pancreatitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Periodontal disease subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Steatorrhoea subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Gastritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Hepatobiliary disorders Hepatic steatosis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Venoocclusive liver disease subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0		
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	12 / 51 (23.53%) 16		
Dry skin subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 3		
Hyperhidrosis subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 6		
Night sweats subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1		
Alopecia			

subjects affected / exposed	4 / 51 (7.84%)			
occurrences (all)	4			
Rash				
subjects affected / exposed	13 / 51 (25.49%)			
occurrences (all)	14			
Rash maculo-papular				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences (all)	3			
Acne				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Pityriasis rosea				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Erythema				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Dermatitis allergic				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Psoriasis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Skin lesion				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Skin exfoliation				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Rash vesicular				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Rash pruritic				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Purpura				

subjects affected / exposed occurrences (all) Skin ulcer subjects affected / exposed occurrences (all) Urticaria subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0 0 / 51 (0.00%) 0 1 / 51 (1.96%) 2		
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all) Dysuria subjects affected / exposed occurrences (all) Cystitis haemorrhagic subjects affected / exposed occurrences (all) Urinary tract pain subjects affected / exposed occurrences (all)	 0 / 51 (0.00%) 0 0 / 51 (0.00%) 0 0 / 51 (0.00%) 0 0 / 51 (0.00%) 0		
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all) Hypothyroidism subjects affected / exposed occurrences (all) Primary hypothyroidism subjects affected / exposed occurrences (all)	 3 / 51 (5.88%) 3 8 / 51 (15.69%) 8 0 / 51 (0.00%) 0		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Arthralgia	 8 / 51 (15.69%) 10		

subjects affected / exposed	11 / 51 (21.57%)			
occurrences (all)	15			
Bone pain				
subjects affected / exposed	8 / 51 (15.69%)			
occurrences (all)	10			
Muscle spasms				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Myalgia				
subjects affected / exposed	7 / 51 (13.73%)			
occurrences (all)	12			
Pain in extremity				
subjects affected / exposed	3 / 51 (5.88%)			
occurrences (all)	3			
Flank pain				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Groin pain				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Joint effusion				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Joint swelling				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Muscle contracture				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Muscle swelling				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Musculoskeletal chest pain				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	2			
Neck pain				

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Osteoporosis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Periarthritis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Plantar fasciitis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	2		
Sinusitis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	3		
Respiratory tract infection			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	3		
Rhinitis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Gastrointestinal infection			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		

Upper respiratory tract infection				
subjects affected / exposed	6 / 51 (11.76%)			
occurrences (all)	9			
Urinary tract infection				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
COVID-19				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Atypical mycobacterial infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Aeromonas infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Bacterial infection				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	2 / 51 (3.92%)			
occurrences (all)	2			
Cellulitis				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Conjunctivitis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Cystitis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			

Folliculitis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Gastric infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Gingivitis				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Herpes simplex				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Lymph gland infection				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Lip infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	1 / 51 (1.96%)			
occurrences (all)	1			
Infection				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Hordeolum				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Infected skin ulcer				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	6 / 51 (11.76%)			
occurrences (all)	7			
Herpes zoster				
subjects affected / exposed	0 / 51 (0.00%)			
occurrences (all)	0			

Tooth infection			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Tooth abscess			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Septic shock			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Pyelonephritis			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Pharyngitis bacterial			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	3		
Oral herpes			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	3		
Hyperglycaemia			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	4		
Hypomagnesaemia			
subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	2		
Hyponatraemia			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Hypokalaemia			

subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	2		
Dehydration			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences (all)	1		
Vitamin B12 deficiency			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 July 2014	The first assessment timepoint was changed to Week 9 to assess patients with early disease progression. Added that study drug administration could begin before the results of a bone marrow biopsy (pathological reports) became available.
04 December 2014	This global amendment is introduced a new cohort (Cohort C) into the study.
23 June 2015	This amendment clarified the timing of analysis for each study cohort.
21 October 2015	This global amendment is introduced a new cohort (Cohort D) into the study.
24 March 2016	This amendment documented the revised timing of primary endpoint analysis for cohorts A and C.
08 September 2016	This amendment introduced a Data Monitoring Committee for Cohort D, a revised protocol Appendix 1 Management Algorithms and a few other minor updates.
22 August 2019	In this protocol revision, subjects switched from a dose of 3 mg/kg every 2 weeks to a flat dose of 480 mg every 4 weeks or a flat dose of 240 mg every 2 weeks by IV infusion over 30 minutes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported