Clinical trial results:
A Phase I/ II Study to Evaluate the Safety and Preliminary Efficacy of Nivolumab in Combination with Brentuximab Vedotin in Subjects with Relapsed Refractory Non Hodgkin Lymphomas with CD30 Expression CheckMate 436: CHECKpoint pathway and nivolumab clinical Trial Evaluation

Summary

EudraCT number	2015-003286-28
Trial protocol	ES FR GB IT
Global end of trial date	07 February 2022

Results information

Result version number	v1 (current)
This version publication date	23 February 2023
First version publication date	23 February 2023

Trial information

Trial identification

Sponsor protocol code	CA209-436

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	Chausse 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	30 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 February 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety profile, tolerability and antitumor activity following administration of nivolumab in combination with brentuximab vedotin in subjects with the diagnosis of relapsed/refractory DLBCL, PTCL (all subtypes excluding ALCL), PMBL. MGZL and CTCL (MF/SS).

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 subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 December 2015
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	Canada: 23
Country: Number of subjects enrolled	France: 15
Country: Number of subjects enrolled	Italy: 46
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	United Kingdom: 47
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	144
EEA total number of subjects	68

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)	108
From 65 to 84 years	35
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The Dose Evaluation Phase (Cohort A) will include a dose limiting toxicity (DLT) evaluation for the dose level of brentuximab vedotin 1.8 mg/kg in combination with nivolumab 240 mg. The reduced dose of brentuximab vedotin at 1.2 mg/kg was not needed based on the safety data reviewed throughout the DLT evaluation period.

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	Diffuse Large B-cell Lymphoma (DLBCL)

Arm description:

1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab

Arm type	Experimental
Investigational medicinal product name	brentuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:

1.8mg/kg q3

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:

240mg

Arm title	Peripheral T-cell Lymphoma (PTCL)

Arm description:

1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab

Arm type	Experimental
Investigational medicinal product name	brentuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:

1.8mg/kg q3

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:
240mg

Arm title	Cutaneous T-cell lymphoma (CTCL)

Arm description:
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab

Arm type	Experimental
Investigational medicinal product name	brentuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:
1.8mg/kg q3

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:
240mg

Arm title	Mediastinal Grey Zone Lymphoma (MGZL)

Arm description:
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab

Arm type	Experimental
Investigational medicinal product name	brentuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:
1.8mg/kg q3

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details:
240mg

Arm title	Primary Mediastinal B-cell Lymphoma (PMBL)

Arm description:
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab

Arm type	Experimental
Investigational medicinal product name	brentuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use

Dosage and administration details: 1.8mg/kg q3	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravascular use
Dosage and administration details: 240mg	

Number of subjects in period 1	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)
Started	42	33	29
Phase 1 DLT evaluable participants	2	1	3
Completed Phase 1 DLT evaluation	2	1	3
Completed	0	0	0
Not completed	42	33	29
Poor/Non-Compliance	-	-	1
Disease progression	29	19	13
Study drug toxicity	4	6	7
Request to discontinue	1	-	3
Other Reasons	1	-	2
Maximum clinical benefit	1	7	1
AE unrelated to study drug	3	1	1
participant withdrew consent	3	-	1

Number of subjects in period 1	Mediastinal Grey Zone Lymphoma (MGZL)	Primary Mediastinal B-cell Lymphoma (PMBL)
Started	10	30
Phase 1 DLT evaluable participants	0	0
Completed Phase 1 DLT evaluation	0	0
Completed	0	0
Not completed	10	30
Poor/Non-Compliance	-	-
Disease progression	5	8
Study drug toxicity	-	3
Request to discontinue	-	1
Other Reasons	2	3
Maximum clinical benefit	3	13
AE unrelated to study drug	-	2
participant withdrew consent	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Diffuse Large B-cell Lymphoma (DLBCL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Peripheral T-cell Lymphoma (PTCL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Cutaneous T-cell lymphoma (CTCL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Mediastinal Grey Zone Lymphoma (MGZL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Primary Mediastinal B-cell Lymphoma (PMBL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	

Reporting group values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)
Number of subjects	42	33	29
Age categorical Units: Subjects			
Adults (18-64 years)	29	21	20
From 65-84 years	12	12	9
85 years and over	1	0	0
Age Continuous Units: Years			
arithmetic mean	57.7	59.1	57.9
standard deviation	± 13.2	± 12.0	± 12.39
Sex: Female, Male Units: Participants			
Female	20	11	13
Male	22	22	16
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	2	5
White	36	30	24
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	2	0
Not Hispanic or Latino	14	13	16
Unknown or Not Reported	27	18	13

Reporting group values	Mediastinal Grey Zone Lymphoma (MGZL)	Primary Mediastinal B-cell Lymphoma (PMBL)	Total
Number of subjects	10	30	144
Age categorical Units: Subjects			
Adults (18-64 years)	9	29	108
From 65-84 years	1	1	35
85 years and over	0	0	1
Age Continuous Units: Years			
arithmetic mean	39.9	37.3	
standard deviation	± 15.2	± 12.9	-
Sex: Female, Male Units: Participants			
Female	4	17	65
Male	6	13	79
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	2	13
White	9	26	125
More than one race	0	0	0
Unknown or Not Reported	0	1	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	4
Not Hispanic or Latino	6	9	58
Unknown or Not Reported	4	20	82

End points

End points reporting groups

Reporting group title	Diffuse Large B-cell Lymphoma (DLBCL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Peripheral T-cell Lymphoma (PTCL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Cutaneous T-cell lymphoma (CTCL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Mediastinal Grey Zone Lymphoma (MGZL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	Primary Mediastinal B-cell Lymphoma (PMBL)
Reporting group description: 1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	

Primary: Safety Analysis - Number of participant deaths

End point title	Safety Analysis - Number of participant deaths[1]
End point description: Number of participant Deaths	
End point type	Primary
End point timeframe: CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 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: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	24	22	3	3

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	5			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Number of participants with adverse advents

End point title	Safety Analysis - Number of participants with adverse

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.

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 Months

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	42	33	29	10

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	30			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Number of participants with serious adverse events

End point title	Safety Analysis - Number of participants with serious adverse events[3]

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.
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- is an important medical event

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 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: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	22	19	14	4

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	10			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Number of participants with adverse events leading to discontinuation

End point title	Safety Analysis - Number of participants with adverse events leading to discontinuation[4]

End point description:

Number of participants with adverse events leading to discontinuation

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 Months

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	11	10	6	2

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	8			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Number of participants with adverse events leading to dose delay or reduction

End point title	Safety Analysis - Number of participants with adverse events leading to dose delay or reduction[5]

End point description:

Number of participants with adverse events leading to dose delay or reduction

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 Months

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	16	15	14	3

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			

Units: Participants	17			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Number of participants with drug related adverse events

End point title	Safety Analysis - Number of participants with drug related adverse events[6]

End point description:

Number of participants with Drug Related Adverse Events

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 Months

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	35	27	25	9

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	25			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Percentage of participants with Thyroid test abnormalities

End point title	Safety Analysis - Percentage of participants with Thyroid test abnormalities[7]

End point description:

Percentage of participants with specific thyroid test abnormalities

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 Months

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	22	9
Units: Percentage of Participants				
number (not applicable)				
TSH > ULN	34.6	29.6	18.2	11.1
TSH > ULN w/ TSH ≤ ULN at baseline	26.9	22.2	18.2	0
TSH > ULN w/at least 1 FT3/FT4 value < LLN	11.5	11.1	13.6	0
TSH > ULN w/all other FT3/FT4 values ≥ LLN	15.4	11.1	0	11.1
TSH > ULN with FT3/FT4 testing missing	7.7	7.4	4.5	0
TSH < LLN	7.7	7.4	4.5	11.1
TSH < LLN w/TSH ≥ LLN at baseline	7.7	0	4.5	0
TSH < LLN w/at least 1 FT3/FT4 value > ULN	0	3.7	4.5	0
TSH < LLN w/ all other FT3/FT4 values ≤ ULN	0	3.7	0	11.1
TSH < LLN w/ FT3/FT4 test missing	7.7	0	0	0

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Percentage of Participants				
number (not applicable)				
TSH > ULN	24.0			
TSH > ULN w/ TSH ≤ ULN at baseline	8.0			
TSH > ULN w/at least 1 FT3/FT4 value < LLN	4.0			
TSH > ULN w/all other FT3/FT4 values ≥ LLN	8.0			
TSH > ULN with FT3/FT4 testing missing	12.0			
TSH < LLN	24.0			
TSH < LLN w/TSH ≥ LLN at baseline	20.0			
TSH < LLN w/at least 1 FT3/FT4 value > ULN	20.0			
TSH < LLN w/ all other FT3/FT4 values ≤ ULN	0			
TSH < LLN w/ FT3/FT4 test missing	4.0			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Percentage of participants with Liver test abnormalities

End point title	Safety Analysis - Percentage of participants with Liver test abnormalities[8]

End point description:

Percentage of participants with specific Liver test abnormalities

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 Months

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Percentage of Participants				
number (not applicable)				
ALT or AST > 3 x ULN	4.8	6.1	13.8	20.0
ALT or AST > 5 x ULN	2.4	0	6.9	10.0
ALT or AST > 10 x ULN	0	0	0	10.0
ALT or AST > 20 x ULN	0	0	0	10.0
Total Bilirubin > 2 x ULN	0	6.1	3.4	20.0
ALT/AST elevation > 3xULN w/Bili >2xULN in 1 day	0	3.0	3.4	10.0
ALT/AST elevation >3xULN w/Bili 2xULN in 30 days	0	3.0	3.4	10.0

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Percentage of Participants				
number (not applicable)				
ALT or AST > 3 x ULN	24.0			
ALT or AST > 5 x ULN	10.0			
ALT or AST > 10 x ULN	6.7			

ALT or AST > 20 x ULN	6.7			
Total Bilirubin > 2 x ULN	3.3			
ALT/AST elevation > 3xULN w/Bili >2xULN in 1 day	3.3			
ALT/AST elevation >3xULN w/Bili 2xULN in 30 days	3.3			

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)[9]

End point description:

The percentage of participants with a best overall response (BOR) of CR or PR.

DLBCL, PTCL, PMBL & MGZL complete and partial response are outlined in the Lugano Classification 2014 and Lymphoma Response to Immunomodulatory therapy Criteria.

CTCL complete and partial response are defined in The consensus Global Response Score assessment.

End point type	Primary

End point timeframe:

CTCL: 20 Months, PTCL: 26.5 Months, DLBCL: 26 Months, MGZL: 30 Months and PMBL 25.5 Months

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Percentage of participants				
number (confidence interval 80%)	28.6 (19.4 to 39.4)	45.5 (33.3 to 58.0)	41.4 (28.8 to 55.0)	70.0 (44.8 to 88.4)

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Percentage of participants				
number (confidence interval 80%)	73.3 (60.3 to 83.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Safety Analysis - Number of participants with dose limiting toxicities (DLT) in the DLT evaluation phase

End point title	Safety Analysis - Number of participants with dose limiting toxicities (DLT) in the DLT evaluation phase[10]

End point description:

DLTs are defined as any study drug-related toxicity (brentuximab vedotin or nivolumab) that requires either a dose reduction or delay of more than 7 days of either study drug in Cycle 2 or delays the Cycle 3 Day 1 administration of combined treatment by more than 7 days.

End point type	Primary

End point timeframe:

From first dose of treatment to 6 weeks after first dose

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis done for this endpoint

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	3	0[11]
Units: Participants	0	0	0	

Notes:

[11] - No subjects with reportable measures

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	0[12]			
Units: Participants				

Notes:

[12] - No subjects with reportable measures

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

DOR will be calculated from the date of initial documentation of a response (CR, or PR) to the date of first documented evidence of progressive disease (or relapse for participants who experience CR during the study) or death due to any cause, whichever occurs first.

DLBCL, PTCL, PMBL & MGZL complete and partial response are outlined in the Lugano Classification 2014 and Lymphoma Response to Immunomodulatory therapy Criteria.

CTCL complete and partial response are defined in The consensus Global Response Score assessment.

Here "99999" means NA

End point type	Secondary

End point timeframe:

From the first patient first visit to 8 months after the last patient first visit (up to 48 months)

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	15	12	7
Units: Months				
median (confidence interval 95%)	3.55 (1.18 to 36.53)	4.60 (2.76 to 12.75)	26.97 (2.79 to 99999)	20.76 (1.22 to 99999)

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: Months				
median (confidence interval 95%)	99999 (23.33 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response Rate (CRR)

End point title	Complete Response Rate (CRR)

End point description:

The CRR is defined as the percentage of participants with a BOR (Best overall response) of CR divided by the number of treated participants.

DLBCL, PTCL, PMBL & MGZL (CR)
1.Complete disappearance of all detectable clinical evidence of disease.
2.Bone marrow: No evidence of FDG- avid disease in marrow.
CTCL (CR)
1. 100% clearance of skin lesions.
2. all lymph nodes ≤1.5 cm, N3 classification and ≤ 1.5 cm in their long axis and > 1 cm in their short axis at baseline, must be ≤ 1 cm in their short axis or biopsy negative for lymphoma.
3. organs should not be enlarged on examination or imaging
4.absence of blood involvement

End point type	Secondary

End point timeframe:

From first dose to the date of initial objectively documented progression or the date of subsequent therapy, whichever occurs first (up to 48 months)

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Percentage of Participants				
number (not applicable)	7.1	33.3	3.4	50.0

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Percentage of Participants				
number (not applicable)	40.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Complete Response

End point title	Duration of Complete Response

End point description:

The duration of CR will only be evaluated in participants with BOR of CR and is defined as the time from first documentation of CR to the date of relapse or death due to any cause, whichever occurs first.

DLBCL, PTCL, PMBL & MGZL (CR)
1.Complete disappearance of all detectable clinical evidence of disease.
2.Bone marrow: No evidence of FDG- avid disease in marrow.
CTCL (CR)
1. 100% clearance of skin lesions.
2. all lymph nodes ≤1.5 cm, N3 classification and ≤ 1.5 cm in their long axis and > 1 cm in their short axis at baseline, must be ≤ 1 cm in their short axis or biopsy negative for lymphoma.
3. organs should not be enlarged on examination or imaging
4.absence of blood involvement

Here "99999" means NA

End point type	Secondary

End point timeframe:

From first dose to the date of relapse or death due to any cause, whichever occurs first. (about 48 months)

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	11	1	5
Units: Months				
median (confidence interval 95%)	36.53 (9.92 to 99999)	7.39 (2.17 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Months				
median (confidence interval 95%)	99999 (27.89 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

PFS is defined as the time from the date of first dose of study drug until the date of first documented evidence of progressive disease (or relapse for participants who experience CR during the study) or death due to any cause, whichever comes first. Participants who are progression-free and alive or have unknown status will be censored at the last tumor assessment. Participants who did not have any onstudy tumor assessments and did not die will be censored on the date of first treatment. For participants who received subsequent therapy prior to documented progression, it will be censored on the last tumor assessment date prior to or on subsequent therapy.

Here "99999" means NA

End point type	Secondary

End point timeframe:

From first dose of study drug until the date of first documented evidence of progressive disease (or relapse for participants who experience CR during the study) or death due to any cause, whichever comes first. (about 48 months)

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Months				
median (confidence interval 95%)	2.60 (1.38 to	4.30 (1.58 to	15.61 (4.86 to	21.88 (0.07 to

2.79)	5.62)	99999)	99999)

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Months				
median (confidence interval 95%)	25.95 (2.63 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS is defined as the time from the date of first dose of study drug until the date of death (any reason). If the participant is alive or the vital status is unknown, the participant will be censored at the date the participant was last known to be alive.

Here "99999" means NA

End point type	Secondary

End point timeframe:

From the first patient first visit to 8 months after the last patient first visit (about 48 months)

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Months				
median (confidence interval 95%)	13.31 (6.57 to 15.87)	11.07 (5.16 to 15.31)	37.16 (18.63 to 99999)	99999 (0.07 to 99999)

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Months				

median (confidence interval 95%)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Safety Analysis - Number of participant deaths - Extended collection

End point title	Safety Analysis - Number of participant deaths - Extended collection

End point description:

Number of participant Deaths

This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 30-March-2022)

End point type	Post-hoc

End point timeframe:

from first date of treatment to final database lock. Approximately 6 years and 7 months.

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	30	26	14	4

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	8			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Safety Analysis - Number of participants with Adverse Events - Extended Collection

End point title	Safety Analysis - Number of participants with Adverse Events - Extended Collection

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.

This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 30-March-2022)

End point type	Post-hoc

End point timeframe:

From first patient first treatment to first to 100 days post last treatment. Approximately 6 years and 4 months.

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	42	33	29	10

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	30			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Safety Analysis - Number of participants with Serious Adverse Events - Extended Collection

End point title	Safety Analysis - Number of participants with Serious Adverse Events - Extended Collection

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.
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- is an important medical event

This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 30-March-

2022)

End point type	Post-hoc

End point timeframe:

From first patient first treatment to first to 100 days post last treatment. Approximately 6 years and 4 months.

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	22	19	14	4

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	10			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Safety Analysis - Number of participants with Adverse Events leading to discontinuation - Extended Collection

End point title	Safety Analysis - Number of participants with Adverse Events leading to discontinuation - Extended Collection

End point description:

Number of Adverse events leading to discontinuation

This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 30-March-2022)

End point type	Post-hoc

End point timeframe:

From first patient first treatment to first to 100 days post last treatment. Approximately 6 years and 4 months.

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	12	11	10	2

End point values	Primary Mediastinal B-cell Lymphoma (PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	9			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Safety Analysis - Number of participants with Drug Related Adverse Events - Extended Collection

End point title	Safety Analysis - Number of participants with Drug Related Adverse Events - Extended Collection

End point description:

Number of Drug Related Adverse Events

This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 30-March-2022)

End point type	Post-hoc

End point timeframe:

From first patient first treatment to first to 100 days post last treatment. Approximately 6 years and 4 months.

End point values	Diffuse Large B-cell Lymphoma (DLBCL)	Peripheral T-cell Lymphoma (PTCL)	Cutaneous T-cell lymphoma (CTCL)	Mediastinal Grey Zone Lymphoma (MGZL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	33	29	10
Units: Participants	35	28	26	9

End point values	Primary Mediastinal B-cell Lymphoma			

	(PMBL)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Participants	25			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first patient first visit to first to final data base lock. Approximately 6 years and 7 months.

All cause mortality is calculated from first treatment to final data base lock.. Approximately 6 years and 7 months.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	DLBCL
Reporting group description:	
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	PMBL
Reporting group description:	
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	MGZL
Reporting group description:	
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	PTCL
Reporting group description:	
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	
Reporting group title	CTCL
Reporting group description:	
1.8mg/kg brentuximab vedotin (BV) + 240mg nivolumab	

Serious adverse events	DLBCL	PMBL	MGZL
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 42 (54.76%)	12 / 30 (40.00%)	5 / 10 (50.00%)
number of deaths (all causes)	30	8	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Lymphoma			

subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Malignant neoplasm progression			
subjects affected / exposed	13 / 42 (30.95%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 14	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 10	0 / 2	0 / 1
Neoplasm malignant			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			
Haematoma			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Haemorrhage			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Hypotension			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
General disorders and administration site conditions			

Chest pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Death			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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 like illness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			
Oedema genital			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			
Atelectasis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Acute respiratory failure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Pneumonitis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 42 (4.76%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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 distress			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Delirium			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lipase increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium test positive			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Transaminases increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			
Fall			
subjects affected / exposed	1 / 42 (2.38%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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			
Aplasia			

subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dysmetria			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	1 / 10 (10.00%)
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 and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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

Febrile neutropenia			
subjects affected / exposed	3 / 42 (7.14%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Colitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Diarrhoea			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Nausea			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Pancreatitis acute			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Hepatotoxicity			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			

subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Skin and subcutaneous tissue disorders			
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (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
Erythema multiforme			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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 / 42 (0.00%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nephroangiosclerosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			
Adrenal insufficiency			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			
Pain in extremity			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Clostridium difficile infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Device related infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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	4 / 42 (9.52%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	2 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Pneumonia pseudomonal			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Sepsis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Vascular device infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Skin infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
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			

Diabetes mellitus			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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
Hypokalaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (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

Serious adverse events	PTCL	CTCL	
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 33 (75.76%)	18 / 29 (62.07%)	
number of deaths (all causes)	26	14	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	9 / 33 (27.27%)	4 / 29 (13.79%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 9	0 / 4	
Neoplasm malignant			

subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Death			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Influenza like illness			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	10 / 33 (30.30%)	2 / 29 (6.90%)	
occurrences causally related to treatment / all	3 / 11	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Oedema genital			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			

subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

Lipase increased			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium test positive			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Aplasia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			

subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Dysmetria			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			

subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			

subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatotoxicity			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

Stevens-Johnson syndrome			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash maculo-papular			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema multiforme			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephroangiosclerosis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Pain in extremity			

subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacteraemia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 33 (6.06%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumonia pseudomonal			

subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus			

subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	DLBCL	PMBL	MGZL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 42 (100.00%)	28 / 30 (93.33%)	9 / 10 (90.00%)
Vascular disorders			
Hot flush			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	4	0	0
Hypotension			
subjects affected / exposed	9 / 42 (21.43%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	10	0	0
Hypertension			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	11 / 42 (26.19%)	4 / 30 (13.33%)	0 / 10 (0.00%)
occurrences (all)	12	4	0
Fatigue			
subjects affected / exposed	16 / 42 (38.10%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences (all)	16	2	1
Chills			

subjects affected / exposed	7 / 42 (16.67%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	11	2	0
Chest pain			
subjects affected / exposed	1 / 42 (2.38%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences (all)	1	3	1
Gait disturbance			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Malaise			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	4 / 42 (9.52%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	4	1	0
Pain			
subjects affected / exposed	1 / 42 (2.38%)	4 / 30 (13.33%)	0 / 10 (0.00%)
occurrences (all)	1	4	0
Peripheral swelling			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Pyrexia			
subjects affected / exposed	13 / 42 (30.95%)	7 / 30 (23.33%)	2 / 10 (20.00%)
occurrences (all)	17	10	3
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	5 / 42 (11.90%)	3 / 30 (10.00%)	1 / 10 (10.00%)
occurrences (all)	5	4	1
Dysphonia			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	4	0	0
Cough			
subjects affected / exposed	10 / 42 (23.81%)	13 / 30 (43.33%)	3 / 10 (30.00%)
occurrences (all)	10	15	4
Pneumonitis			

subjects affected / exposed	2 / 42 (4.76%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal pain			
subjects affected / exposed	4 / 42 (9.52%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	4	4	0
Nasal congestion			
subjects affected / exposed	2 / 42 (4.76%)	1 / 30 (3.33%)	1 / 10 (10.00%)
occurrences (all)	2	1	2
Hypoxia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	6 / 42 (14.29%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	7	1	0
Productive cough			
subjects affected / exposed	4 / 42 (9.52%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	9	3	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 42 (7.14%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	3	2	0
Insomnia			
subjects affected / exposed	5 / 42 (11.90%)	2 / 30 (6.67%)	2 / 10 (20.00%)
occurrences (all)	6	2	2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	2 / 10 (20.00%)
occurrences (all)	0	1	3
Amylase increased			
subjects affected / exposed	1 / 42 (2.38%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Blood alkaline phosphatase increased			

subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Blood creatinine increased			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	3	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Lipase increased			
subjects affected / exposed	2 / 42 (4.76%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	2 / 42 (4.76%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	6	4	0
Platelet count decreased			
subjects affected / exposed	1 / 42 (2.38%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Weight decreased			
subjects affected / exposed	4 / 42 (9.52%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences (all)	4	2	1
Weight increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Infusion related reaction			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	1 / 10 (10.00%)
occurrences (all)	0	1	2
Procedural nausea			
subjects affected / exposed	0 / 42 (0.00%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	2 / 42 (4.76%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Tachycardia			
subjects affected / exposed	2 / 42 (4.76%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences (all)	2	2	1
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	14 / 42 (33.33%)	9 / 30 (30.00%)	0 / 10 (0.00%)
occurrences (all)	15	11	0
Paraesthesia			
subjects affected / exposed	3 / 42 (7.14%)	2 / 30 (6.67%)	3 / 10 (30.00%)
occurrences (all)	3	2	3
Headache			
subjects affected / exposed	6 / 42 (14.29%)	6 / 30 (20.00%)	0 / 10 (0.00%)
occurrences (all)	9	6	0
Dysgeusia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 42 (2.38%)	5 / 30 (16.67%)	2 / 10 (20.00%)
occurrences (all)	1	5	2
Dizziness			

subjects affected / exposed	3 / 42 (7.14%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 42 (11.90%)	3 / 30 (10.00%)	6 / 10 (60.00%)
occurrences (all)	8	3	6
Eosinophilia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Thrombocytopenia			
subjects affected / exposed	5 / 42 (11.90%)	5 / 30 (16.67%)	3 / 10 (30.00%)
occurrences (all)	8	8	4
Neutropenia			
subjects affected / exposed	8 / 42 (19.05%)	13 / 30 (43.33%)	4 / 10 (40.00%)
occurrences (all)	20	23	5
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	10 / 42 (23.81%)	4 / 30 (13.33%)	0 / 10 (0.00%)
occurrences (all)	15	5	0
Abdominal pain lower			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 42 (0.00%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	20 / 42 (47.62%)	4 / 30 (13.33%)	0 / 10 (0.00%)
occurrences (all)	41	6	0
Constipation			
subjects affected / exposed	9 / 42 (21.43%)	5 / 30 (16.67%)	1 / 10 (10.00%)
occurrences (all)	13	5	1
Dyspepsia			

subjects affected / exposed	2 / 42 (4.76%)	3 / 30 (10.00%)	0 / 10 (0.00%)
occurrences (all)	3	4	0
Dysphagia			
subjects affected / exposed	3 / 42 (7.14%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	4	1	0
Flatulence			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 42 (0.00%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Haemorrhoids			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 42 (0.00%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	17 / 42 (40.48%)	5 / 30 (16.67%)	0 / 10 (0.00%)
occurrences (all)	20	9	0
Toothache			
subjects affected / exposed	0 / 42 (0.00%)	2 / 30 (6.67%)	1 / 10 (10.00%)
occurrences (all)	0	2	1
Vomiting			
subjects affected / exposed	9 / 42 (21.43%)	3 / 30 (10.00%)	0 / 10 (0.00%)
occurrences (all)	10	5	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Alopecia			
subjects affected / exposed	4 / 42 (9.52%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	5	1	0
Night sweats			
subjects affected / exposed	6 / 42 (14.29%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	10	2	0
Rash maculo-papular			
subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	3
Rash macular			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	5 / 42 (11.90%)	6 / 30 (20.00%)	0 / 10 (0.00%)
occurrences (all)	7	8	0
Pruritus			
subjects affected / exposed	3 / 42 (7.14%)	4 / 30 (13.33%)	1 / 10 (10.00%)
occurrences (all)	4	5	1
Petechiae			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			

Hyperthyroidism			
subjects affected / exposed	0 / 42 (0.00%)	4 / 30 (13.33%)	0 / 10 (0.00%)
occurrences (all)	0	4	0
Hypothyroidism			
subjects affected / exposed	1 / 42 (2.38%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 42 (19.05%)	6 / 30 (20.00%)	1 / 10 (10.00%)
occurrences (all)	11	7	1
Bone pain			
subjects affected / exposed	1 / 42 (2.38%)	1 / 30 (3.33%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Back pain			
subjects affected / exposed	3 / 42 (7.14%)	3 / 30 (10.00%)	1 / 10 (10.00%)
occurrences (all)	3	3	1
Pain in extremity			
subjects affected / exposed	4 / 42 (9.52%)	3 / 30 (10.00%)	1 / 10 (10.00%)
occurrences (all)	5	4	1
Neck pain			
subjects affected / exposed	1 / 42 (2.38%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Muscular weakness			
subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Muscle spasms			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	3	0	1
Infections and infestations			
Ear infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			

subjects affected / exposed	3 / 42 (7.14%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	3	2	0
Influenza			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Oral candidiasis			
subjects affected / exposed	2 / 42 (4.76%)	2 / 30 (6.67%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Pneumonia			
subjects affected / exposed	5 / 42 (11.90%)	1 / 30 (3.33%)	2 / 10 (20.00%)
occurrences (all)	5	1	3
Rhinitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	4	0	0
Skin infection			
subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Staphylococcal infection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 30 (3.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 42 (7.14%)	3 / 30 (10.00%)	0 / 10 (0.00%)
occurrences (all)	5	3	0
Urinary tract infection			
subjects affected / exposed	4 / 42 (9.52%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	6	0	2
Viral infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Diabetes mellitus			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	8 / 42 (19.05%)	3 / 30 (10.00%)	2 / 10 (20.00%)
occurrences (all)	11	3	2
Hyperuricaemia			
subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	2 / 10 (20.00%)
occurrences (all)	2	0	3
Hyperkalaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 42 (4.76%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	5	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	3 / 42 (7.14%)	0 / 30 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Hypomagnesaemia			
subjects affected / exposed	6 / 42 (14.29%)	1 / 30 (3.33%)	3 / 10 (30.00%)
occurrences (all)	10	1	4
Hypokalaemia			
subjects affected / exposed	9 / 42 (21.43%)	0 / 30 (0.00%)	3 / 10 (30.00%)
occurrences (all)	11	0	3
Hypocalcaemia			
subjects affected / exposed	4 / 42 (9.52%)	0 / 30 (0.00%)	1 / 10 (10.00%)
occurrences (all)	4	0	1

Non-serious adverse events	PTCL	CTCL	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 33 (100.00%)	28 / 29 (96.55%)	
Vascular disorders			

Hot flush			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	4 / 33 (12.12%)	2 / 29 (6.90%)	
occurrences (all)	4	2	
Hypertension			
subjects affected / exposed	3 / 33 (9.09%)	3 / 29 (10.34%)	
occurrences (all)	3	3	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	7 / 33 (21.21%)	5 / 29 (17.24%)	
occurrences (all)	7	7	
Fatigue			
subjects affected / exposed	15 / 33 (45.45%)	8 / 29 (27.59%)	
occurrences (all)	18	8	
Chills			
subjects affected / exposed	2 / 33 (6.06%)	2 / 29 (6.90%)	
occurrences (all)	3	2	
Chest pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Malaise			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Oedema peripheral			
subjects affected / exposed	2 / 33 (6.06%)	7 / 29 (24.14%)	
occurrences (all)	2	7	
Pain			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Peripheral swelling			

subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	12 / 33 (36.36%)	14 / 29 (48.28%)	
occurrences (all)	20	17	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	7 / 33 (21.21%)	4 / 29 (13.79%)	
occurrences (all)	7	4	
Dysphonia			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences (all)	1	2	
Cough			
subjects affected / exposed	9 / 33 (27.27%)	6 / 29 (20.69%)	
occurrences (all)	9	9	
Pneumonitis			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Oropharyngeal pain			
subjects affected / exposed	3 / 33 (9.09%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Nasal congestion			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences (all)	3	2	
Hypoxia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Dyspnoea exertional			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Productive cough			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Psychiatric disorders			

Anxiety			
subjects affected / exposed	2 / 33 (6.06%)	2 / 29 (6.90%)	
occurrences (all)	2	2	
Insomnia			
subjects affected / exposed	1 / 33 (3.03%)	4 / 29 (13.79%)	
occurrences (all)	1	4	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	6 / 33 (18.18%)	2 / 29 (6.90%)	
occurrences (all)	7	3	
Amylase increased			
subjects affected / exposed	3 / 33 (9.09%)	3 / 29 (10.34%)	
occurrences (all)	4	3	
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 33 (18.18%)	3 / 29 (10.34%)	
occurrences (all)	8	4	
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Blood bilirubin increased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Blood creatinine increased			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 33 (9.09%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Lipase increased			
subjects affected / exposed	3 / 33 (9.09%)	4 / 29 (13.79%)	
occurrences (all)	3	6	
Lymphocyte count decreased			
subjects affected / exposed	3 / 33 (9.09%)	2 / 29 (6.90%)	
occurrences (all)	3	3	
Neutrophil count decreased			

subjects affected / exposed	5 / 33 (15.15%)	0 / 29 (0.00%)	
occurrences (all)	8	0	
Platelet count decreased			
subjects affected / exposed	3 / 33 (9.09%)	2 / 29 (6.90%)	
occurrences (all)	3	2	
Weight decreased			
subjects affected / exposed	2 / 33 (6.06%)	3 / 29 (10.34%)	
occurrences (all)	2	3	
Weight increased			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
White blood cell count decreased			
subjects affected / exposed	2 / 33 (6.06%)	1 / 29 (3.45%)	
occurrences (all)	3	1	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Infusion related reaction			
subjects affected / exposed	4 / 33 (12.12%)	6 / 29 (20.69%)	
occurrences (all)	4	18	
Procedural nausea			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	0 / 33 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Nervous system disorders			

Neuropathy peripheral			
subjects affected / exposed	5 / 33 (15.15%)	9 / 29 (31.03%)	
occurrences (all)	5	12	
Paraesthesia			
subjects affected / exposed	5 / 33 (15.15%)	1 / 29 (3.45%)	
occurrences (all)	5	1	
Headache			
subjects affected / exposed	3 / 33 (9.09%)	4 / 29 (13.79%)	
occurrences (all)	7	4	
Dysgeusia			
subjects affected / exposed	3 / 33 (9.09%)	1 / 29 (3.45%)	
occurrences (all)	3	1	
Peripheral sensory neuropathy			
subjects affected / exposed	5 / 33 (15.15%)	3 / 29 (10.34%)	
occurrences (all)	5	3	
Dizziness			
subjects affected / exposed	3 / 33 (9.09%)	1 / 29 (3.45%)	
occurrences (all)	4	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 33 (30.30%)	1 / 29 (3.45%)	
occurrences (all)	25	1	
Eosinophilia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	8 / 33 (24.24%)	1 / 29 (3.45%)	
occurrences (all)	10	1	
Neutropenia			
subjects affected / exposed	9 / 33 (27.27%)	0 / 29 (0.00%)	
occurrences (all)	23	0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 33 (6.06%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	9 / 33 (27.27%)	1 / 29 (3.45%)	
occurrences (all)	12	1	
Abdominal pain lower			
subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences (all)	4	2	
Abdominal pain upper			
subjects affected / exposed	2 / 33 (6.06%)	2 / 29 (6.90%)	
occurrences (all)	4	3	
Diarrhoea			
subjects affected / exposed	14 / 33 (42.42%)	15 / 29 (51.72%)	
occurrences (all)	27	21	
Constipation			
subjects affected / exposed	8 / 33 (24.24%)	3 / 29 (10.34%)	
occurrences (all)	11	3	
Dyspepsia			
subjects affected / exposed	2 / 33 (6.06%)	4 / 29 (13.79%)	
occurrences (all)	2	4	
Dysphagia			
subjects affected / exposed	2 / 33 (6.06%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Flatulence			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Haemorrhoids			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Stomatitis			
subjects affected / exposed	2 / 33 (6.06%)	1 / 29 (3.45%)	
occurrences (all)	3	1	
Nausea			
subjects affected / exposed	12 / 33 (36.36%)	10 / 29 (34.48%)	
occurrences (all)	18	11	

Toothache			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	8 / 33 (24.24%)	3 / 29 (10.34%)	
occurrences (all)	12	3	
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 33 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Dry skin			
subjects affected / exposed	4 / 33 (12.12%)	2 / 29 (6.90%)	
occurrences (all)	4	2	
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 33 (0.00%)	4 / 29 (13.79%)	
occurrences (all)	0	4	
Alopecia			
subjects affected / exposed	3 / 33 (9.09%)	3 / 29 (10.34%)	
occurrences (all)	4	3	
Night sweats			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Rash maculo-papular			
subjects affected / exposed	2 / 33 (6.06%)	3 / 29 (10.34%)	
occurrences (all)	2	3	
Rash macular			
subjects affected / exposed	0 / 33 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Rash			
subjects affected / exposed	9 / 33 (27.27%)	4 / 29 (13.79%)	
occurrences (all)	13	8	
Pruritus			
subjects affected / exposed	10 / 33 (30.30%)	8 / 29 (27.59%)	
occurrences (all)	13	10	
Petechiae			

subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Skin exfoliation			
subjects affected / exposed	0 / 33 (0.00%)	3 / 29 (10.34%)	
occurrences (all)	0	3	
Skin lesion			
subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Skin ulcer			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 33 (3.03%)	3 / 29 (10.34%)	
occurrences (all)	1	3	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 33 (21.21%)	4 / 29 (13.79%)	
occurrences (all)	9	4	
Bone pain			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Back pain			
subjects affected / exposed	6 / 33 (18.18%)	1 / 29 (3.45%)	
occurrences (all)	6	1	
Pain in extremity			
subjects affected / exposed	4 / 33 (12.12%)	0 / 29 (0.00%)	
occurrences (all)	5	0	
Neck pain			

subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences (all)	2	2	
Myalgia			
subjects affected / exposed	1 / 33 (3.03%)	3 / 29 (10.34%)	
occurrences (all)	1	3	
Muscular weakness			
subjects affected / exposed	3 / 33 (9.09%)	1 / 29 (3.45%)	
occurrences (all)	3	1	
Muscle spasms			
subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Infections and infestations			
Ear infection			
subjects affected / exposed	1 / 33 (3.03%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Nasopharyngitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	2 / 33 (6.06%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Herpes zoster			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
Oral candidiasis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Pneumonia			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
Rhinitis			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Sinusitis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	

Skin infection			
subjects affected / exposed	0 / 33 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	2	
Staphylococcal infection			
subjects affected / exposed	0 / 33 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Upper respiratory tract infection			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Urinary tract infection			
subjects affected / exposed	2 / 33 (6.06%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Viral infection			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 33 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Decreased appetite			
subjects affected / exposed	6 / 33 (18.18%)	5 / 29 (17.24%)	
occurrences (all)	9	6	
Hyperuricaemia			
subjects affected / exposed	1 / 33 (3.03%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
Hyperkalaemia			
subjects affected / exposed	0 / 33 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Hyperglycaemia			
subjects affected / exposed	4 / 33 (12.12%)	0 / 29 (0.00%)	
occurrences (all)	4	0	
Hypoalbuminaemia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Hypercalcaemia			

subjects affected / exposed	0 / 33 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	5 / 33 (15.15%)	1 / 29 (3.45%)	
occurrences (all)	5	1	
Hypokalaemia			
subjects affected / exposed	4 / 33 (12.12%)	1 / 29 (3.45%)	
occurrences (all)	10	1	
Hypocalcaemia			
subjects affected / exposed	5 / 33 (15.15%)	0 / 29 (0.00%)	
occurrences (all)	9	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 September 2016	This amendment will allow additional cohorts in subjects with relapsed PMBL & MGZL to participate in the expansion cohort. Additionally, the amendment will also provide defined Indeterminate response (IR) criteria along with changes in the biomarker section. Minor clarification in the inclusion, exclusion criteria and clarification of dose adjustment for brentuximab vedotin for grade 3 neurological toxicity has also been updated

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported