Clinical trial results:
A Phase Ib/II Study Evaluating the Safety and Efficacy of Obinutuzumab in Combination With Idasanutlin and Venetoclax in Patients With Relapsed or Refractory Follicular Lymphoma and Obinutuzumab or Rituximab in Combination With Idasanutlin and Venetoclax in Patie.nts With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Summary

EudraCT number	2016-002480-34
Trial protocol	DE
Global end of trial date	30 April 2020

Results information

Result version number	v1 (current)
This version publication date	14 May 2021
First version publication date	14 May 2021

Trial information

Trial identification

Sponsor protocol code	BH39147

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03135262
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann- La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.com
Scientific contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, +41 61 6878333, global-roche-genentech-trials@gene.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 September 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2020
Global end of trial reached?	Yes
Global end of trial date	30 April 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

A Study of Obinutuzumab in Combination With Idasanutlin and Venetoclax in Participants With Relapsed or Refractory (R/R) Follicular Lymphoma (FL) or Rituximab in Combination With Idasanutlin and Venetoclax in Participants With R/R Diffuse Large B-Cell Lymphoma (DLBCL).

Protection of trial subjects:

The study was conducted in accordance with the principles of the "Declaration of Helsinki" and Good Clinical Practice (GCP) guidelines according to the regulations and procedures described in the protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 6
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Korea, Republic of: 4
Country: Number of subjects enrolled	New Zealand: 6
Country: Number of subjects enrolled	United States: 8
Worldwide total number of subjects	29
EEA total number of subjects	5

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)	11

From 65 to 84 years	18
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

29 Subjects (ITT population) were enrolled at 13 sites in the USA, Australia, South Korea, New Zealand and Germany during the dose escalation phase. 1 subject was undefined as the diagnosis at study entry was not provided.

Pre-assignment

Screening details:

The study was prematurely terminated after Escalation Phase because of the overall modest benefit achieved with MTD during the escalation phase.

In each DLBCL and FL arm, subjects are in Safety Cohort, Cohort 1, Cohort 2, Cohort 3 and Cohort 3-Not defined (DLBCL only). All Adverse Events are reported per Cohort rather than per Arm.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dose Escalation DLBCL and FL Safety Cohort

Arm description:

Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 100 milligrams (mg) idasanutlin orally, once daily for 5 days, every 28 days, until treatment discontinuation

Arm title	Dose Escalation DLBCL and FL Cohort 1

Arm description:

Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 100 milligrams (mg) idasanutlin orally, once daily for 5 days, every 28 days, until treatment discontinuation

Arm title	Dose Escalation DLBCL and FL Cohort 2

Arm description:

Idasanutlin 150 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg

Arm type	Experimental

Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 150 milligrams (mg) idasanutlin orally, once daily for 5 days, every 28 days, until treatment discontinuation

Arm title	Dose Escalation DLBCL and FL Cohort 3

Arm description:

Idasanutlin 100 mg + Venetoclax 400 mg + Obinutuzumab 1000 mg

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 100 milligrams (mg) idasanutlin orally, once daily for 5 days, every 28 days, until treatment discontinuation

Arm title	Not Defined DLBCL only Cohort 3

Arm description:

Not defined

Arm type	Experimental
Investigational medicinal product name	Not defined
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Not defined

Number of subjects in period 1	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2
Started	9	6	7
Completed	0	0	0
Not completed	9	6	7
Adverse event, serious fatal	6	2	2
Consent withdrawn by subject	-	-	1
Discontinued due to pre-existing medical condition	1	-	-
Study terminated by sponsor	2	4	4
Progression of disease	-	-	-

Number of subjects in period 1	Dose Escalation DLBCL and FL Cohort 3	Not Defined DLBCL only Cohort 3
Started	6	1

Completed	0	0
Not completed	6	1
Adverse event, serious fatal	2	-
Consent withdrawn by subject	-	1
Discontinued due to pre-existing medical condition	-	-
Study terminated by sponsor	3	-
Progression of disease	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Dose Escalation DLBCL and FL Safety Cohort
Reporting group description: Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg	
Reporting group title	Dose Escalation DLBCL and FL Cohort 1
Reporting group description: Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg	
Reporting group title	Dose Escalation DLBCL and FL Cohort 2
Reporting group description: Idasanutlin 150 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg	
Reporting group title	Dose Escalation DLBCL and FL Cohort 3
Reporting group description: Idasanutlin 100 mg + Venetoclax 400 mg + Obinutuzumab 1000 mg	
Reporting group title	Not Defined DLBCL only Cohort 3
Reporting group description: Not defined	

Reporting group values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2
Number of subjects	9	6	7
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	2	2
From 65-84 years	3	4	5
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	58.6	68.5	72.4
standard deviation	± 15.5	± 8.7	± 8.6
Sex: Female, Male Units: Subjects			
Female	3	3	3
Male	6	3	4
Race (NIH/OMB) Units: Subjects			
Not Hispanic or Latino	9	6	7
Hispanic or Latino	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			

Asian	2	0	1
White	7	5	6
Black or African American	0	0	0
Unknown	0	1	0

Reporting group values	Dose Escalation DLBCL and FL Cohort 3	Not Defined DLBCL only Cohort 3	Total
Number of subjects	6	1	29
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	1	11
From 65-84 years	6	0	18
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	74.3	25.0	
standard deviation	± 5.5	± 999	-
Sex: Female, Male Units: Subjects			
Female	3	0	12
Male	3	1	17
Race (NIH/OMB) Units: Subjects			
Not Hispanic or Latino	6	1	29
Hispanic or Latino	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Asian	2	0	5
White	2	1	21
Black or African American	1	0	1
Unknown	1	0	2

End points

End points reporting groups

Reporting group title	Dose Escalation DLBCL and FL Safety Cohort
Reporting group description: Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg	
Reporting group title	Dose Escalation DLBCL and FL Cohort 1
Reporting group description: Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg	
Reporting group title	Dose Escalation DLBCL and FL Cohort 2
Reporting group description: Idasanutlin 150 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg	
Reporting group title	Dose Escalation DLBCL and FL Cohort 3
Reporting group description: Idasanutlin 100 mg + Venetoclax 400 mg + Obinutuzumab 1000 mg	
Reporting group title	Not Defined DLBCL only Cohort 3
Reporting group description: Not defined	

Primary: RP2D of Idasanutlin When Given in Combination With Obinutuzumab or Rituximab

End point title	RP2D of Idasanutlin When Given in Combination With Obinutuzumab or Rituximab[1]

End point description:

It was planned to be identified in escalation and carried over in expansion phases. However the expansion phase did not take place. phases.

The study was closed because at escalation doses 100 and 150 mg Idasanutlin, the benefit was mild. The study was terminated at the escalation phase with DLTs showing AEs in all cohorts. The subpopulations of DLBCL and FL were showed no difference in their genetic subtype make-up, therefore, Cohorts Safety, 1, 2, 3 contain both populations.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 up to Cycle 2 Day 28 (each cycle = 28 days)

Notes:

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

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: mg				
number (not applicable)	0	0	150	100

End point values	Not Defined			

	DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: mg				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: RP2D of Venetoclax When Given in Combination With Obinutuzumab or Rituximab

End point title	RP2D of Venetoclax When Given in Combination With Obinutuzumab or Rituximab[2]

End point description:

It was planned to be identified in escalation and carried over in expansion phases. However the expansion phase did not take place.

The study was closed because at escalation doses 200 and 400 mg Venetoclax, the benefit was mild. The study was terminated at the escalation phase with DLTs showing AEs in all cohorts.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 up to Cycle 2 Day 28 (each cycle = 28 days)

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: Only descriptive statistics was planned to be reported in the endpoint.

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: mg	0	0	200	400

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: mg	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Dose-Limiting Toxicities (DLTs)

End point title	Percentage of Subjects With Dose-Limiting Toxicities (DLTs)[3]

End point description:

DLT is defined as any one of the following events occurring during first two Cycles of treatment and assessed by the investigator as clearly not related to patient's underlying disease: - Any Grade 5 adverse event (AE) unless unequivocally due to the underlying malignancy or extraneous causes; - AE of any grade that leads to a delay of more than 14 days at the start of next treatment cycle; - Hematologic AEs (neutropenia, thrombocytopenia); - Non-hematologic AE, except IRRs, laboratory TLS without manifestations of clinical TLS, AST or ALT, diarrhea, nausea or vomiting, fatigue, asthenia, anorexia, or constipation, hepatic transaminase.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 up to Cycle 2 Day 28 (each cycle = 28 days)

Notes:

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

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: Percentage of Subjects				
number (not applicable)	0	16.7	28.6	16.7

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of Subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs)

End point title	Percentage of Subjects With Adverse Events (AEs)[4]

End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a casual relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events.

End point type	Primary

End point timeframe:

From Baseline up to approximately 48 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: Only descriptive statistics was planned to be reported in the endpoint.

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: Percentage of Subjects				
number (not applicable)	100	100	100	100

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of Subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Complete Response (CR), Determined by an Independent Review Committee (IRC) on the Basis of Positron Emission Tomography-Computed Tomography (PET-CT) Scans Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With Complete Response (CR), Determined by an Independent Review Committee (IRC) on the Basis of Positron Emission Tomography-Computed Tomography (PET-CT) Scans Using Modified Lugano 2014 Criteria[5]

End point description:

The study plan was for the IRC to analyze the efficacy results in participants from the expansion phase (Part II), but the expansion phase was not opened (i.e., no enrollment) because the sponsor decided to terminate the study early due to the modest benefit achieved with the maximum tolerated dose during the dose escalation phase (Part I). Therefore the result data not derived and not reported.

End point type	Primary

End point timeframe:

At end of Induction (EOI) (within 6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days])

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: Only descriptive statistics was planned to be reported in the endpoint.

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[6]	0[7]	0[8]	0[9]
Units: Percentage of Subjects				
number (not applicable)				

Notes:

[6] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[7] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[8] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[9] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	0[10]			
Units: Percentage of Subjects				
number (not applicable)				

Notes:

[10] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With CR, Determined by the Investigator on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With CR, Determined by the Investigator on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria

End point description:

The investigator evaluated responses at the end of induction treatment using Lugano 2014 criteria for malignant lymphoma for a PET-CT based complete response (CR), which required a complete metabolic response with a score of 1, 2 or 3 with or without a residual mass in lymph nodes and extralymphatic sites on the PET 5-point scale for 18-fluorodeoxyglucose (FDG) uptake (1 = no uptake above background; 2 = uptake less than or equal to [<=] mediastinum; 3 = uptake greater than [>] mediastinum and <= liver; 4 = uptake moderately > liver; 5 = uptake markedly > liver and/or new lesions). The CR criteria were slightly modified to require normal bone marrow by morphology (if intermediate, immunohistochemistry negative). PET-CT scans were performed at end of induction only on participants who had received at least 2 cycles of induction treatment; those without a post-baseline tumor assessment were considered non-responders.

End point type	Secondary

End point timeframe:

At EOI (6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days]

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: Percentage of Subjects				
number (confidence interval 90%)	22.2 (4.10 to 54.96)	16.7 (0.85 to 58.18)	28.6 (5.34 to 65.87)	16.7 (0.85 to 58.18)

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of Subjects				
number (confidence interval 90%)	0 (0 to 95.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With CR, Determined by the IRC on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With CR, Determined by the IRC on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point description:

The IRC was to evaluate responses at the end of induction treatment using the Lugano 2014 response criteria for malignant lymphoma for a computed tomography (CT)-based complete response (CR). The CR criteria required to complete radiologic response with all of the following: target nodal masses must regress to less than or equal to 1.5 centimeters in the longest transverse diameter of a lesion [LDi]; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunochemistry negative). CT scans were performed at end of induction only on participants who had received at least 2 cycles of induction treatment; those without a post-baseline tumor assessment were to be considered non-responders. Therefore the result data not derived and not reported.

End point type	Secondary

End point timeframe:

At EOI (6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days]

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	0[12]	0[13]	0[14]
Units: Percentage of Subjects				

Notes:

[11] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[12] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[13] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[14] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	0[15]			
Units: Percentage of Subjects				

Notes:

[15] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With CR, Determined by the Investigator on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With CR, Determined by the Investigator on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point description:

The investigator evaluated responses at the end of induction treatment using the Lugano 2014 response criteria for malignant lymphoma for a computed tomography (CT)-based complete response (CR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 centimeters in the longest transverse diameter of a lesion (LDi); no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). CT scans were performed at end of induction only on participants who received at least 2 cycles of Induction treatment; those without a post-baseline tumor assessment were to be considered non-responders. This outcome measure therefore not derived and not reported.

End point type	Secondary

End point timeframe:

At EOI (6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days]

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[16]	0[17]	0[18]	0[19]
Units: Percentage of Subjects				

Notes:

[16] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[17] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[18] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[19] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

End point values	Not Defined DLBCL only Cohort 3			

Subject group type	Reporting group			
Number of subjects analysed	0[20]			
Units: Percentage of Subjects				

Notes:

[20] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Objective Response, Determined by the IRC on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With Objective Response, Determined by the IRC on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria

End point description:

The IRC was to evaluate responses at the end of induction treatment using Luagno 2014 criteria for malignant lymphoma for a PET-CT based objective response: either a complete (CR) or partial response (PR). A CR required a complete metabolic response with a score of 1, 2 or 3 on the PET 5-point scale (5PS) for 18-fluorodeoxyglucose (FDG) uptake (scores range from 1 [no uptake above background] to 5 [uptake markedly higher than liver and/or new lesions]), with or without a residual mass in lymph nodes and extralymphatic sites; and a PR required a partial metabolic response with a score 4 or 5 on the 5PS with reduced 18-FDG uptake compared with baseline and residual mass(es) of any size. For bone marrow involvement, the CR criteria required no evidence of FDG-avid disease, and the PR criteria required residual uptake higher than in normal marrow but reduced compared with baseline. The study was pre-maturely terminated.

End point type	Secondary

End point timeframe:

At EOI (6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days]

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[21]	0[22]	0[23]	0[24]
Units: Percentage of Subjects				

Notes:

[21] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[22] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[23] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[24] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	0[25]			
Units: Percentage of Subjects				

Notes:

[25] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Objective Response, Determined by the Investigator on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects with Objective Response, Determined by the Investigator on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria

End point description:

The investigator was to evaluate responses at end of induction treatment using Lugano 2014 criteria for malignant lymphoma for a PET-CT based objective response: either a complete (CR) or partial response (PR). A CR required a complete metabolic response with a score of 1, 2, or 3 on the PET 5-point scale (5PS) for 18-fluorodeoxyglucose (FDG) uptake (scores range from 1 [no uptake above background] to 5 [uptake markedly higher than liver and/or new lesions]), with or without a residual mass in lymph nodes and extralymphatic sites; and a PR required a partial metabolic response with a score of 4 or 5 on the 5PS with reduced 18-FDG uptake compared with baseline and residual mass(es) of any size. For bone marrow involvement, the CR criteria required no evidence of FDG-avid disease, and the PR criteria required residual uptake higher than in normal marrow but reduced compared with baseline. The study was terminated after escalation phase and no result data derived.

End point type	Secondary

End point timeframe:

At EOI (6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days]

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: Percentage of Subjects				
number (confidence interval 90%)	33.3 (9.77 to 65.51)	16.7 (0.85 to 58.18)	28.6 (5.34 to 65.87)	33.3 (6.28 to 72.87)

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of Subjects				
number (confidence interval 90%)	0 (0 to 95.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Objective Response, Determined by the IRC on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With Objective Response, Determined

	by the IRC on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point description:

The IRC was to evaluate responses at the end of induction treatment using the Lugano 2014 response criteria for malignant lymphoma for a CT-based objective response: either a complete (CR) or partial response (PR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 cm in the LDi; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). The PR criteria required all of the following: a >=50% decrease in sum of the product of perpendicular diameters of up to 6 target measurable nodes and extranodal sites; no new lesions; non-measured lesion that is absent/nomal, regressed, but no increase; and spleen must have regressed by >50% in length. Because of early termination, no result data derived.

End point type	Secondary

End point timeframe:

At EOI (6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days]

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[26]	0[27]	0[28]	0[29]
Units: Percentage of Subjects				

Notes:

[26] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[27] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[28] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[29] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	0[30]			
Units: Percentage of Subjects				

Notes:

[30] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Objective Response at EOI, Determined by the Investigator on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With Objective Response at EOI, Determined by the Investigator on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point description:

The investigator was to evaluate responses at the end of induction treatment using Lugano 2014 response criteria for malignant lymphoma for a CT-based objective response: either a complete (CR) or partial response (PR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 cm in LDi; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). The PR criteria

required all of the following: a >=50% decrease in sum of the product of perpendicular diameters up to 6 target measurable nodes and extranodal sites; no new lesions; non-measured lesion that is absent/normal, regressed, but no increase; and spleen must have regressed by >50% in length. Because of early termination, the result did not derive.

End point type	Secondary

End point timeframe:

At EOI (6 to 8 weeks after Cycle 6 Day 1 [up to approximately 28 weeks] [each cycle = 28 days]

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[31]	0[32]	0[33]	0[34]
Units: Percentage of Subjects				

Notes:

[31] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[32] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[33] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[34] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	0[35]			
Units: Percentage of Subjects				

Notes:

[35] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Objective Response During the Study, Determined by the Investigator on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point title	Percentage of Subjects With Objective Response During the Study, Determined by the Investigator on the Basis of CT Scans Alone Using Modified Lugano 2014 Criteria

End point description:

The investigator was to evaluate responses during the study treatment using Luagno 2014 response criteria for malignant lymphoma for a CT-based objective response: either a complete (CR) or partial response (PR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 cm in the LDi; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). The PR criteria required all of the following: a >=50% decrease in sum of the product of perpendicular diameters up to 6 target measurable nodes and extranodal sites; no new lesions; non-measured lesion that is absent/normal, regressed, but no increase; and spleen must have regressed by >50% in length. Because of early termination, the result did not derive.

End point type	Secondary

End point timeframe:

From Day 1 of Cycle 1 (cycle length = 28 days) up to approximately 48 months

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[36]	0[37]	0[38]	0[39]
Units: Percentage of Subjects				

Notes:

[36] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[37] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[38] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

[39] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	0[40]			
Units: Percentage of Subjects				

Notes:

[40] - The study was terminated after escalation phase due to mile benefit by the sponsor's decision.

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Concentration of Obinutuzumab in Subjects With FL

End point title	Observed Serum Concentration of Obinutuzumab in Subjects With FL

End point description:

Observed Serum Concentration of Obinutuzumab in Participants With FL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated. No result data was derived, therefore no result was reported.
The result data not derived due to early termination of the study by the sponsor's decision and did not reach the end of study.

End point type	Secondary

End point timeframe:

From Day 1 of Cycle 1 (cycle length = 28 days) up to approximately 48 months (detailed timeframe is mentioned in outcome measure description)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: mg				

number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: mg				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Concentration of Obinutuzumab in Subjects With DLBCL

End point title	Observed Serum Concentration of Obinutuzumab in Subjects With DLBCL

End point description:

Observed Serum Concentration of Obinutuzumab in Participants With DLBCL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated. No result data was derived, therefore no result was reported.

End point type	Secondary

End point timeframe:

Induction: Pre-dose (any time prior to dose on same day) and 30 min post-dose on Day 1 of Cycle 1; Pre-dose (within 5 hrs prior to dose) and 30 min post-dose on Day 1 of Cycles 2, 4 and 6 (each cycle = 28 days)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: pg/ml				
number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: pg/ml				

number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Concentration of Rituximab in Subjects With FL

End point title	Observed Serum Concentration of Rituximab in Subjects With FL

End point description:

Observed Serum Concentration of Rituximab in Participants With FL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated. No result data was derived, therefore no result was reported.

End point type	Secondary

End point timeframe:

Induction: Pre-dose (any time prior to dose on same day) on Day 1 of Cycle 1; Pre-dose (within 5 hrs prior to dose) on Day 1 of Cycles 2, 4, 6; 30 min post-dose on Day 1 of Cycles 1 and 6 (each cycle = 28 days)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: pg/ml				
number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: pg/ml				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Concentration of Rituximab in Subjects With DLBCL

End point title	Observed Serum Concentration of Rituximab in Subjects With DLBCL

End point description:

Observed Serum Concentration of Rituximab in Participants With DLBCL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated. No result data was derived, therefore no result was reported.

End point type	Secondary

End point timeframe:

From Day 1 of Cycle 1 (cycle length = 28 days) up to approximately 48 months (detailed timeframe is mentioned in outcome measure description)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: pg/ml				
number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: pg/ml				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Concentration of Idasanutlin in Subjects With FL

End point title	Observed Plasma Concentration of Idasanutlin in Subjects With FL

End point description:

Observed Plasma Concentration of Idasanutlin in Participants With FL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated. No result data was derived therefore no result was reported

End point type	Secondary

End point timeframe:

From Day 1 of Cycle 1 up to Day 5 of Cycle 4 (each cycle = 28 days) (detailed timeframe is mentioned in outcome measure description)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: pg/ml				
number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: pg/ml				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Concentration of Idasanutlin in Subjectss With DLBCL

End point title	Observed Plasma Concentration of Idasanutlin in Subjectss With DLBCL

End point description:

Observed Plasma Concentration of Idasanutlin in Participants With DLBCL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated. No result data was derived therefore no result was reported

End point type	Secondary

End point timeframe:

From Day 1 of Cycle 1 up to Day 5 of Cycle 4 (each cycle = 28 days) (detailed timeframe is mentioned in outcome measure description)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: pg/ml				
number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: pg/ml				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Concentration of Venetoclax in Subjects With FL

End point title	Observed Plasma Concentration of Venetoclax in Subjects With FL

End point description:

Observed Plasma Concentration of Venetoclax in Participants With FL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated.

End point type	Secondary

End point timeframe:

From Day 1 of Cycle 1 up to Day 5 of Cycle 4 (each cycle = 28 days) (detailed timeframe is mentioned in outcome measure description)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: pg/ml				
number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: pg/ml				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Concentration of Venetoclax in Subjects With DLBCL

End point title	Observed Plasma Concentration of Venetoclax in Subjects With DLBCL

End point description:

Observed Plasma Concentration of Venetoclax in Subjects With DLBCL was planned to be determined as part of the pharmacokinetics analyses during the expansion phase which did not take place.
The study was prematurely terminated because of the overall modest benefit achieved with MTD during the escalation phase (Part 1); Phase II of the study (expansion) was never initiated.

End point type	Secondary

End point timeframe:

From Day 1 of Cycle 1 up to Day 5 of Cycle 4 (each cycle = 28 days) (detailed timeframe is mentioned in outcome measure description)

End point values	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2	Dose Escalation DLBCL and FL Cohort 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	6	7	6
Units: pg/ml				
number (not applicable)	0	0	0	0

End point values	Not Defined DLBCL only Cohort 3			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: pg/ml				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline until after the last dose of study drug treatment

Adverse event reporting additional description:

Reported: Safety Population. During the Safety Follow-up Period, non-Serious Adverse Events occurred at the 5% frequency threshold. There was no non-SAEs occurred reported in Dose Escalation DLBCL only Cohort 3 Not Defined arm.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Dose Escalation DLBCL and FL Safety Cohort

Reporting group description:

Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg

Reporting group title	Dose Escalation DLBCL and FL Cohort 1

Reporting group description:

Idasanutlin 100 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg

Reporting group title	Dose Escalation DLBCL and FL Cohort 2

Reporting group description:

Idasanutlin 150 mg + Venetoclax 200 mg + Obinutuzumab 1000 mg

Reporting group title	Dose Escalation DLBCL and FL Cohort 3

Reporting group description:

Idasanutlin 100 mg + Venetoclax 400 mg + Obinutuzumab 1000 mg

Reporting group title	DLBCL Only Not Defined Cohort

Reporting group description:

Not defines

Serious adverse events	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 9 (33.33%)	3 / 6 (50.00%)	4 / 7 (57.14%)
number of deaths (all causes)	6	2	2
number of deaths resulting from adverse events			
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (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 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (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 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
NEUTROPENIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
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 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLECYSTITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
OSTEOARTHRITIS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (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			
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (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	Dose Escalation DLBCL and FL Cohort 3	DLBCL Only Not Defined Cohort	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	0 / 1 (0.00%)	
number of deaths (all causes)	2	0	
number of deaths resulting from adverse events			
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (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 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (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			
HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (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 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
NEUTROPENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (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	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
OSTEOARTHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
DEVICE RELATED INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (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	Dose Escalation DLBCL and FL Safety Cohort	Dose Escalation DLBCL and FL Cohort 1	Dose Escalation DLBCL and FL Cohort 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	6 / 6 (100.00%)	7 / 7 (100.00%)
Vascular disorders			

DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
HYPOTENSION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
LYMPHATIC FISTULA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
THROMBOPHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
CHEST PAIN			
subjects affected / exposed	0 / 9 (0.00%)	3 / 6 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
CHILLS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
FATIGUE			
subjects affected / exposed	1 / 9 (11.11%)	3 / 6 (50.00%)	3 / 7 (42.86%)
occurrences (all)	1	3	3
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
OEDEMA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
PAIN			

subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
UNEVALUABLE EVENT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	2 / 9 (22.22%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
EPISTAXIS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
DELIRIUM			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
DEPRESSION			

subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Investigations			
ALANINE AMINOTRANSFERASE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
AMYLASE INCREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 9 (22.22%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
RESPIROVIRUS TEST POSITIVE			

subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
SERUM FERRITIN INCREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
WEIGHT DECREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	4	0	5
Injury, poisoning and procedural complications			
ACCIDENTAL OVERDOSE			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
CONTUSION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	3 / 9 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
MEDICATION ERROR			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
PRODUCT ADMINISTRATION ERROR			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
PRODUCT DOSE OMISSION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
WOUND COMPLICATION			

subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
WRONG TECHNIQUE IN PRODUCT USAGE PROCESS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	2 / 9 (22.22%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	4	1	1
HEADACHE			
subjects affected / exposed	3 / 9 (33.33%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	5	2	2
NEURALGIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
PARAESTHESIA			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
RADICULAR PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

ANAEMIA			
subjects affected / exposed	4 / 9 (44.44%)	1 / 6 (16.67%)	4 / 7 (57.14%)
occurrences (all)	5	1	4
LEUKOPENIA			
subjects affected / exposed	3 / 9 (33.33%)	1 / 6 (16.67%)	3 / 7 (42.86%)
occurrences (all)	3	1	8
LYMPHOPENIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	7 / 9 (77.78%)	5 / 6 (83.33%)	7 / 7 (100.00%)
occurrences (all)	13	8	20
THROMBOCYTOPENIA			
subjects affected / exposed	7 / 9 (77.78%)	4 / 6 (66.67%)	7 / 7 (100.00%)
occurrences (all)	9	5	13
Eye disorders			
EYE DISORDER			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
EYE PAIN			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
PHOTOPHOBIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
VISION BLURRED			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	2
ABDOMINAL PAIN			
subjects affected / exposed	3 / 9 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
ANAL INCONTINENCE			

subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
CONSTIPATION			
subjects affected / exposed	2 / 9 (22.22%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
DIARRHOEA			
subjects affected / exposed	5 / 9 (55.56%)	3 / 6 (50.00%)	4 / 7 (57.14%)
occurrences (all)	9	3	6
DYSPEPSIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	3 / 9 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
NAUSEA			
subjects affected / exposed	6 / 9 (66.67%)	4 / 6 (66.67%)	3 / 7 (42.86%)
occurrences (all)	14	6	3
ODYNOPHAGIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
STOMATITIS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
TONGUE HAEMATOMA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
VOMITING			
subjects affected / exposed	3 / 9 (33.33%)	3 / 6 (50.00%)	1 / 7 (14.29%)
occurrences (all)	5	3	1

Skin and subcutaneous tissue disorders			
ERYTHEMA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
ERYTHEMA AB IGNE			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
HYPERHIDROSIS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
NIGHT SWEATS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
PAIN OF SKIN			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
RASH			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
HAEMATURIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
MICTURITION URGENCY			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			

subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
BACK PAIN			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
BONE PAIN			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
FLANK PAIN			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
JOINT STIFFNESS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
MYALGIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	2 / 9 (22.22%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
SPINAL OSTEOARTHRITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
VERTEBRAL FORAMINAL STENOSIS			

subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
CELLULITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
GASTROENTERITIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
HERPES ZOSTER			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
MUCOSAL INFECTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
SINUSITIS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	3 / 9 (33.33%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
WOUND INFECTION			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
DIABETES MELLITUS			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
GOUT			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 9 (22.22%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

HYPOPHAGIA			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Dose Escalation DLBCL and FL Cohort 3	DLBCL Only Not Defined Cohort	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	0 / 1 (0.00%)	
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
FLUSHING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPOTENSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
LYMPHATIC FISTULA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
THROMBOPHLEBITIS SUPERFICIAL			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CHILLS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	

FATIGUE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PYREXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
UNEVALUABLE EVENT			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
EPISTAXIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NASAL CONGESTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
PRODUCTIVE COUGH			

subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DELIRIUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DEPRESSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
INSOMNIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Investigations			
ALANINE AMINOTRANSFERASE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
AMYLASE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
LYMPHOCYTE COUNT DECREASED			

subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RESPIROVIRUS TEST POSITIVE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
SERUM FERRITIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
WEIGHT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	2 / 6 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	7	0	
Injury, poisoning and procedural complications			
ACCIDENTAL OVERDOSE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
CONTUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
MEDICATION ERROR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PRODUCT ADMINISTRATION ERROR			

subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PRODUCT DOSE OMISSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
SKIN ABRASION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
WOUND COMPLICATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
WRONG TECHNIQUE IN PRODUCT USAGE PROCESS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HEADACHE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PARAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RADICULAR PAIN			

subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
SYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	3 / 6 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	6	0	
LEUKOPENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
LYMPHOPENIA			
subjects affected / exposed	2 / 6 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
NEUTROPENIA			
subjects affected / exposed	5 / 6 (83.33%)	0 / 1 (0.00%)	
occurrences (all)	21	0	
THROMBOCYTOPENIA			
subjects affected / exposed	5 / 6 (83.33%)	0 / 1 (0.00%)	
occurrences (all)	6	0	
Eye disorders			
EYE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
EYE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PHOTOPHOBIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VISION BLURRED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ANAL INCONTINENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
CONSTIPATION			
subjects affected / exposed	2 / 6 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
DIARRHOEA			
subjects affected / exposed	4 / 6 (66.67%)	0 / 1 (0.00%)	
occurrences (all)	10	0	
DYSPEPSIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
FLATULENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MOUTH ULCERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NAUSEA			
subjects affected / exposed	3 / 6 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	8	0	
ODYNOPHAGIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
STOMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
TONGUE HAEMATOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
VOMITING			
subjects affected / exposed	2 / 6 (33.33%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			
ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
ERYTHEMA AB IGNE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPERHIDROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
NIGHT SWEATS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PAIN OF SKIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RASH			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			

subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
DYSURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MICTURITION URGENCY			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
URINARY RETENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
BONE PAIN			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
FLANK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
JOINT STIFFNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MUSCULOSKELETAL PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MYALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
SPINAL OSTEOARTHRITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
VERTEBRAL FORAMINAL STENOSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
CELLULITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GASTROENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HERPES ZOSTER			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
MUCOSAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

ORAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
SINUSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
WOUND INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
DIABETES MELLITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
GOUT			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
HYPOCALCAEMIA			

subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
HYPOKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
HYPOPHAGIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Dose expansion part of the study did not take place. AEs were not differentiated for DLBCL and FL arms since these are sub mutations of disease which does nor show differences in AEs.

Notes: