Clinical trial results:
A Phase 1b/2a Basket Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Combination Therapy With the Anti-CD19 Monoclonal Antibody Tafasitamab and the PI3K delta Inhibitor Parsaclisib in Adult Participants With Relapsed/Refractory Non-Hodgkin Lymphoma or Chronic Lymphocytic Leukemia (topMIND)

Summary

EudraCT number	2020-005591-35
Trial protocol	FR IT ES AT BE
Global end of trial date	22 October 2024

Results information

Result version number	v1
This version publication date	06 November 2025
First version publication date	06 November 2025

Trial information

Trial identification

Sponsor protocol code	INCMOR 0208-101

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 855-463-3463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 855-463-3463, medinfo@incyte.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	22 October 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The dose confirmation period (Phase 1b was conducted to determine the safety, tolerability, and dose-limiting toxicities of combination therapy with tafasitamab plus parsaclisib in participants with relapsed or refractory (R/R) B-cell malignancies who were previously treated with at least two prior lines of systemic anti-lymphoma therapy. The dose expansion period (Phase 2a) was conducted to assess the preliminary efficacy of combination therapy with tafasitamab plus parsaclisib in participants with R/R B-cell malignancies who were previously treated with at least two prior lines of systemic anti-lymphoma therapy.

Protection of trial subjects:

This study was performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, applicable Good Clinical Practices, and applicable laws and country-specific regulations in which the study was being conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 September 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	Italy: 28
Worldwide total number of subjects	54
EEA total number of subjects	54

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	17
From 65 to 84 years	36
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were enrolled across 16 sites in Austria, Belgium, Spain, France, and Italy.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: R/R DLBCL

Arm description:

Participants with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) received tafasitamab administered at 12 milligrams per kilograms (mg/kg) intravenously (IV) on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg once daily (QD) for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

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

Dosage and administration details:

Dose formulation: 1 mg, 2.5 mg, 5 mg, and 20 mg
tablets. Unit dose strength(s)/dosage level(s): 20 mg, 10 mg 2.5 mg, 1 mg

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

Dosage and administration details:

200 mg lyophilized powder in single-dose 20-mL vial
for reconstitution and dilution

Arm title	Cohort 2: R/R MCL

Arm description:

Participants with R/R mantle cell lymphoma (MCL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Arm type	Experimental

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

Dosage and administration details:

Dose formulation: 1 mg, 2.5 mg, 5 mg, and 20 mg
tablets. Unit dose strength(s)/dosage level(s): 20 mg, 10 mg 2.5 mg, 1 mg

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

Dosage and administration details:

200 mg lyophilized powder in single-dose 20-mL vial
for reconstitution and dilution

Arm title	Cohort 3: R/R FL

Arm description:

Participants with R/R follicular lymphoma (FL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

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

Dosage and administration details:

Dose formulation: 1 mg, 2.5 mg, 5 mg, and 20 mg
tablets. Unit dose strength(s)/dosage level(s): 20 mg, 10 mg 2.5 mg, 1 mg

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

Dosage and administration details:

200 mg lyophilized powder in single-dose 20-mL vial
for reconstitution and dilution

Arm title	Cohort 4: R/R MZL

Arm description:

Participants with R/R marginal zone lymphoma (MZL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

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

Dosage and administration details:

Dose formulation: 1 mg, 2.5 mg, 5 mg, and 20 mg

tablets. Unit dose strength(s)/dosage level(s): 20 mg, 10 mg 2.5 mg, 1 mg

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

Dosage and administration details:

200 mg lyophilized powder in single-dose 20-mL vial
for reconstitution and dilution

Arm title	Cohort 5: R/R CLL/SLL

Arm description:

Participants with R/R chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

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

Dosage and administration details:

Dose formulation: 1 mg, 2.5 mg, 5 mg, and 20 mg
tablets. Unit dose strength(s)/dosage level(s): 20 mg, 10 mg 2.5 mg, 1 mg

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

Dosage and administration details:

200 mg lyophilized powder in single-dose 20-mL vial
for reconstitution and dilution

Number of subjects in period 1	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 3: R/R FL
Started	15	11	21
Completed	0	0	0
Not completed	15	11	21
Adverse event, serious fatal	9	7	4
Consent withdrawn by subject	2	1	3
New Treatment per Principal Investigator	-	-	1
Sponsor Terminated Collection of Follow-up Data	3	2	10
Medical Decision: Worsening Clinical Condition	1	-	-
Transitioned to Rollover Protocol	-	1	2
Lost to follow-up	-	-	1

Number of subjects in period 1	Cohort 4: R/R MZL	Cohort 5: R/R CLL/SLL
Started	3	4
Completed	0	0
Not completed	3	4
Adverse event, serious fatal	-	1
Consent withdrawn by subject	1	-
New Treatment per Principal Investigator	-	-
Sponsor Terminated Collection of Follow-up Data	1	2
Medical Decision: Worsening Clinical Condition	-	-
Transitioned to Rollover Protocol	-	1
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Cohort 1: R/R DLBCL
Reporting group description:	
Participants with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) received tafasitamab administered at 12 milligrams per kilograms (mg/kg) intravenously (IV) on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg once daily (QD) for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.	
Reporting group title	Cohort 2: R/R MCL
Reporting group description:	
Participants with R/R mantle cell lymphoma (MCL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.	
Reporting group title	Cohort 3: R/R FL
Reporting group description:	
Participants with R/R follicular lymphoma (FL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.	
Reporting group title	Cohort 4: R/R MZL
Reporting group description:	
Participants with R/R marginal zone lymphoma (MZL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.	
Reporting group title	Cohort 5: R/R CLL/SLL
Reporting group description:	
Participants with R/R chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.	

Reporting group values	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 3: R/R FL
Number of subjects	15	11	21
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)	4	3	8
From 65-84 years	11	7	13
85 years and over	0	1	0

Age Continuous Units: years			
arithmetic mean	67.2	68.9	66.8
standard deviation	± 15.47	± 15.06	± 8.03
Sex: Female, Male Units: participants			
Female	5	1	11
Male	10	10	10
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	14	9	18
More than one race	0	0	0
Unknown or Not Reported	1	2	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	3	2
Not Hispanic or Latino	13	6	16
Unknown or Not Reported	1	2	3

Reporting group values	Cohort 4: R/R MZL	Cohort 5: R/R CLL/SLL	Total
Number of subjects	3	4	54
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)	1	1	17
From 65-84 years	2	3	36
85 years and over	0	0	1
Age Continuous Units: years			
arithmetic mean	65.7	70.3	
standard deviation	± 17.21	± 5.74	-
Sex: Female, Male Units: participants			
Female	3	2	22
Male	0	2	32
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	3	47
More than one race	0	0	0
Unknown or Not Reported	0	1	7
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	7
Not Hispanic or Latino	2	2	39
Unknown or Not Reported	0	2	8

End points

End points reporting groups

Reporting group title	Cohort 1: R/R DLBCL

Reporting group description:

Participants with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) received tafasitamab administered at 12 milligrams per kilograms (mg/kg) intravenously (IV) on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg once daily (QD) for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 2: R/R MCL

Reporting group description:

Participants with R/R mantle cell lymphoma (MCL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 3: R/R FL

Reporting group description:

Participants with R/R follicular lymphoma (FL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 4: R/R MZL

Reporting group description:

Participants with R/R marginal zone lymphoma (MZL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 5: R/R CLL/SLL

Reporting group description:

Participants with R/R chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Subject analysis set title	All Cohorts
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with R/R DLBCL, R/R, MCL, R/R FL, R/R MZL, and CLL/SLL received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Primary: Phase 1b: Number of participants with dose-limiting toxicities (DLTs)

End point title	Phase 1b: Number of participants with dose-limiting toxicities (DLTs)[1]

End point description:

A DLT was defined as the occurrence of any protocol-defined toxicity up to and including Day 28 (Cycle 1/Day 28), except those with a clear alternative explanation. DLT Evaluable Population: all participants who received at least 3 of 4 doses of tafasitamab and 21 days of treatment with parsaclisib 20 mg QD during the first cycle (28 days) or experienced a DLT.

End point type	Primary

End point timeframe:

up to 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: Statistical analysis was not conducted for this endpoint.

End point values	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 3: R/R FL	Cohort 4: R/R MZL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15[2]	11[3]	21[4]	3[5]
Units: participants	0	0	0	0

Notes:

[2] - DLT Evaluable Population

[3] - DLT Evaluable Population

[4] - DLT Evaluable Population

[5] - DLT Evaluable Population

End point values	Cohort 5: R/R CLL/SLL			
Subject group type	Reporting group			
Number of subjects analysed	4[6]			
Units: participants	0			

Notes:

[6] - DLT Evaluable Population

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1b: Number of participants with any ≥Grade 3 TEAE

End point title	Phase 1b: Number of participants with any ≥Grade 3 TEAE[7]

End point description:

An AE is any untoward medical occurrence associated with the use of a drug in humans, whether or not it is considered drug related. A TEAE is any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug until 90 days after the last dose of study drug. The severity of AEs was assessed using CTCAE v5.0 Grades 1 through 5. Grade 1: mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; treatment not indicated. Grade 2: moderate; minimal, local, or noninvasive treatment indicated; limiting age-appropriate activities of daily living. Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living. Grade 4: life-threatening consequences; urgent treatment indicated. Grade 5: fatal.

End point type	Primary

End point timeframe:

up to 1092 days

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: Statistical analysis was not conducted for this endpoint.

End point values	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 3: R/R FL	Cohort 4: R/R MZL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15[8]	11[9]	21[10]	3[11]
Units: participants	12	9	18	3

Notes:

[8] - Full Analysis Set

[9] - Full Analysis Set

[10] - Full Analysis Set

[11] - Full Analysis Set

End point values	Cohort 5: R/R CLL/SLL			
Subject group type	Reporting group			
Number of subjects analysed	4[12]			
Units: participants	2			

Notes:

[12] - Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1b: Number of participants with any treatment-emergent adverse event (TEAE)

End point title	Phase 1b: Number of participants with any treatment-emergent adverse event (TEAE)[13]

End point description:

An adverse event (AE) is any untoward medical occurrence associated with the use of a drug in humans, whether or not it is considered drug related. An AE can therefore be any unfavorable or unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment. A TEAE is any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug until 90 days after the last dose of study drug. Full Analysis Set: all participants who received at least 1 dose of tafasitamab or parsaclisib.

End point type	Primary

End point timeframe:

up to 1092 days

Notes:

[13] - 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: Statistical analysis was not conducted for this endpoint.

End point values	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 3: R/R FL	Cohort 4: R/R MZL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15[14]	11[15]	21[16]	3[17]
Units: participants	15	11	21	3

Notes:

[14] - Full Analysis Set

[15] - Full Analysis Set

[16] - Full Analysis Set

[17] - Full Analysis Set

End point values	Cohort 5: R/R CLL/SLL			

Subject group type	Reporting group			
Number of subjects analysed	4[18]			
Units: participants	4			

Notes:

[18] - Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2a: Objective response rate based on investigator assessment: percentage of participants with CR/CMR or PR/PMR according to Lugano criteria for NHL and International Working Group for Chronic Lymphocytic Leukemia (iwCLL) criteria for CLL

End point title	Phase 2a: Objective response rate based on investigator assessment: percentage of participants with CR/CMR or PR/PMR according to Lugano criteria for NHL and International Working Group for Chronic Lymphocytic Leukemia (iwCLL) criteria for CLL[19]

End point description:

Lugano complete response/complete metabolic response (CR/CMR): target nodes/masses of lymph nodes/extralymphatic sites (LNs/ELSs) regressed to ≤1.5 cm; no non-measured lesions; organ enlargement regressed to normal; no new lesions (NNLs); normal bone marrow. Lugano partial response/partial metabolic response (PR/PMR): LNs/ELSs, ≥50% decrease in the product of perpendicular diameters sum for multiple lesions; no/regressed non-measured lesions, no increase; organ enlargement; NNLs. iwCLL CR: no LNs ≥1.5 cm; spleen size <13 cm/liver size normal; no constitutional symptoms; normal circulating lymphocyte count (CLC); ≥100 × 10^9 platelets/L; hemoglobin ≥11 g/dL; normocellular, no CLL cells, no B-lymphoid nodules in marrow. iwCLL PR decrease of ≥50% in lymph nodes, liver and/or spleen, and CLC from baseline; constitutional symptoms; ≥100 × 10^9 platelets/L or increase of ≥50% over baseline in platelet count and hemoglobin; presence of CLL cells, or of B-lymphoid nodules, or not done.

End point type	Primary

End point timeframe:

up to 1002 days

Notes:

[19] - 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: Statistical analysis was not conducted for this endpoint.

End point values	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 3: R/R FL	Cohort 4: R/R MZL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15[20]	11[21]	21[22]	3[23]
Units: percentage of participants				
number (confidence interval 95%)	33.3 (11.8 to 61.6)	81.8 (48.2 to 97.7)	90.5 (69.6 to 98.8)	33.3 (0.8 to 90.6)

Notes:

[20] - Full Analysis Set. CIs were calculated based on the exact method for binomial distributions.

[21] - Full Analysis Set. CIs were calculated based on the exact method for binomial distributions.

[22] - Full Analysis Set. CIs were calculated based on the exact method for binomial distributions.

[23] - Full Analysis Set. CIs were calculated based on the exact method for binomial distributions.

End point values	Cohort 5: R/R CLL/SLL			
Subject group type	Reporting group			
Number of subjects analysed	4[24]			
Units: percentage of participants				

number (confidence interval 95%)	50.0 (6.8 to 93.2)			

Notes:

[24] - Full Analysis Set. CIs were calculated based on the exact method for binomial distributions.

Statistical analyses

No statistical analyses for this end point

Secondary: tmax of tafasitamab when given in combination with parsaclisib

End point title	tmax of tafasitamab when given in combination with parsaclisib

End point description:

tmax was defined as the time to the maximum concentration of tafasitamab. Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	53[25]			
Units: hours				
arithmetic mean (standard deviation)	3.963 (± 1.591)			

Notes:

[25] - PK Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of tafasitamab when given in combination with parsaclisib

End point title	Cmax of tafasitamab when given in combination with parsaclisib

End point description:

Cmax was defined as the maximum observed plasma or serum concentration of tafasitamab. Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose. Pharmacokinetic (PK) Evaluable Population: all participants who received at least 1 dose of tafasitamab or parsaclisib and provided at least 1 postdose PK plasma sample.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	53[26]			
Units: milligrams per liter (mg/L)				
arithmetic mean (standard deviation)	324.203 (± 112.746)			

Notes:

[26] - PK Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of tafasitamab when given in combination with parsaclisib

End point title	AUClast of tafasitamab when given in combination with parsaclisib

End point description:

AUClast was defined as the area under the plasma concentration-time curve from time zero to the time of the last measurable concentration. Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	53[27]			
Units: hours x mg/L				
arithmetic mean (standard deviation)	31379.84 (± 12369.81)			

Notes:

[27] - PK Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: VZ of tafasitamab when given in combination with parsaclisib

End point title	VZ of tafasitamab when given in combination with parsaclisib

End point description:

Vz was defined as the volume of distribution. Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr

postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	51[28]			
Units: liters				
arithmetic mean (standard deviation)	3.254 (± 1.694)			

Notes:

[28] - PK Evaluable Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: CL of tafasitamab when given in combination with parsaclisib

End point title	CL of tafasitamab when given in combination with parsaclisib

End point description:

CL was defined as the apparent total body clearance of drug from plasma. Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	51[29]			
Units: liter per hour				
arithmetic mean (standard deviation)	0.021 (± 0.015)			

Notes:

[29] - PK Evaluable Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC0-inf of tafasitamab when given in combination with parsaclisib

End point title	AUC0-inf of tafasitamab when given in combination with parsaclisib

End point description:

AUC0-inf was defined as the area under the plasma concentration-time curve from time zero to infinity (time that the drug is no longer present in the body). Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	51[30]			
Units: hours x mg/L				
arithmetic mean (standard deviation)	54825.21 (± 29363.32)			

Notes:

[30] - PK Evaluable Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Clast of tafasitamab when given in combination with parsaclisib

End point title	Clast of tafasitamab when given in combination with parsaclisib

End point description:

AUC0-inf was defined as the last measurable plasma drug concentration. Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	53[31]			
Units: mg/L				
arithmetic mean (standard deviation)	114.386 (± 56.789)			

Notes:

[31] - PK Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of tafasitamab when given in combination with parsaclisib

End point title	t1/2 of tafasitamab when given in combination with parsaclisib

End point description:

t1/2 was defined as the drug's elimination half-life, which is the time it takes for the concentration of a drug in the body to decrease by 50%. Samples were collected for pharmacokinetic analysis at the following times: Cyle 1 Day 1 (C1D1): predose; immediately after tafasitamab infusion; 1 and 4 hours (hr) postinfusion. C1D8, C1D15, C1D22: predose; immediately after tafasitamab infusion; 1 hr postinfusion. C2D1, C2D15, C3D1, C3D15: predose; 1 hr postinfusion. C4D1 and every 4 cycles thereafter (C8D1, C12D1, etc.): predose.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1, 8, 15, and 22; Cycle 2 Days 1 and 15; Cycle 3 Days 1 and 15; Cycle 4 Day 1 and every 4 cycles thereafter (Cycle 8 Day 1, Cycle 12 Day 1, etc.)

End point values	All Cohorts			
Subject group type	Subject analysis set			
Number of subjects analysed	51[32]			
Units: hours				
arithmetic mean (standard deviation)	121.702 (± 49.506)			

Notes:

[32] - PK Evaluable Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

up to 1092 days

Adverse event reporting additional description:

Adverse events have been reported for the Full Analysis Set, comprised of all participants who received at least 1 dose of tafasitamab or parsaclisib.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22

Reporting groups

Reporting group title	Cohort 1: R/R DLBCL

Reporting group description:

Participants with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) received tafasitamab administered at 12 milligrams per kilograms (mg/kg) intravenously (IV) on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg once daily (QD) for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 2: R/R MCL

Reporting group description:

Participants with R/R mantle cell lymphoma (MCL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 5: R/R CLL/SLL

Reporting group description:

Participants with R/R chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 4: R/R MZL

Reporting group description:

Participants with R/R marginal zone lymphoma (MZL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Reporting group title	Cohort 3: R/R FL

Reporting group description:

Participants with R/R follicular lymphoma (FL) received tafasitamab administered at 12 mg/kg IV on Days 1, 8, 15, and 22 of Cycles 1 through 3 and then Days 1 and 15 of each 28-day cycle from Cycle 4 onward. Participants also self-administered parsaclisib at a dose of 20 mg QD for 8 weeks, followed by a dose of 2.5 mg QD thereafter. Study treatment was administered until progression of disease, withdrawal of consent, or unacceptable toxicity.

Serious adverse events	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 5: R/R CLL/SLL
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 15 (40.00%)	7 / 11 (63.64%)	3 / 4 (75.00%)
number of deaths (all causes)	9	7	1
number of deaths resulting from adverse events	2	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign lung neoplasm			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
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			
Humerus fracture			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (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
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (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
Neutropenia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Malaise			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (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
Pyrexia			
subjects affected / exposed	1 / 15 (6.67%)	2 / 11 (18.18%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Xerosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
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			
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (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
Skin and subcutaneous tissue disorders			
Skin exfoliation			

subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (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
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (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
COVID-19			
subjects affected / exposed	1 / 15 (6.67%)	4 / 11 (36.36%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
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	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (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

Campylobacter gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (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
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (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

Serious adverse events	Cohort 4: R/R MZL	Cohort 3: R/R FL	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	12 / 21 (57.14%)	
number of deaths (all causes)	0	4	
number of deaths resulting from adverse events	0	1	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign lung neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
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			
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (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			

Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (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 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Xerosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	6 / 21 (28.57%)	
occurrences causally related to treatment / all	0 / 0	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (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			
COVID-19 pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 21 (14.29%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus colitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			

subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (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	Cohort 1: R/R DLBCL	Cohort 2: R/R MCL	Cohort 5: R/R CLL/SLL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 15 (100.00%)	11 / 11 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
POEMS syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	4
Hypotension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 15 (33.33%)	3 / 11 (27.27%)	2 / 4 (50.00%)
occurrences (all)	5	6	3
Face oedema			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
General physical health deterioration			
subjects affected / exposed	2 / 15 (13.33%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	2 / 15 (13.33%)	2 / 11 (18.18%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Pyrexia			
subjects affected / exposed	3 / 15 (20.00%)	3 / 11 (27.27%)	0 / 4 (0.00%)
occurrences (all)	5	3	0
Xerosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Immune system disorders			
Graft versus host disease in skin			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Graft versus host disease in liver			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Hypogammaglobulinaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Testicular oedema			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bronchiectasis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	2 / 15 (13.33%)	4 / 11 (36.36%)	3 / 4 (75.00%)
occurrences (all)	3	6	4
Epistaxis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Productive cough			

subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 15 (0.00%)	3 / 11 (27.27%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	2 / 15 (13.33%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
C-reactive protein increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Blood glucose increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Eosinophil count increased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Liver function test abnormal			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Neutrophil count decreased			
subjects affected / exposed	2 / 15 (13.33%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Platelet count decreased			
subjects affected / exposed	3 / 15 (20.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
Weight decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Pelvic bone injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysgraphia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Headache			

subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Anaemia			
subjects affected / exposed	2 / 15 (13.33%)	4 / 11 (36.36%)	2 / 4 (50.00%)
occurrences (all)	2	5	3
Cytopenia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	1	4
Febrile neutropenia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lymphocytosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	7 / 15 (46.67%)	6 / 11 (54.55%)	0 / 4 (0.00%)
occurrences (all)	12	11	0

Thrombocytopenia			
subjects affected / exposed	0 / 15 (0.00%)	7 / 11 (63.64%)	1 / 4 (25.00%)
occurrences (all)	0	8	1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eyelid ptosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Xerophthalmia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	2 / 15 (13.33%)	2 / 11 (18.18%)	0 / 4 (0.00%)
occurrences (all)	4	3	0
Abdominal pain upper			
subjects affected / exposed	0 / 15 (0.00%)	2 / 11 (18.18%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	4 / 15 (26.67%)	2 / 11 (18.18%)	2 / 4 (50.00%)
occurrences (all)	6	2	2
Frequent bowel movements			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal hypermotility			

subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gingival bleeding			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Oesophagitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 15 (13.33%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 11 (18.18%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Eczema asteatotic			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Rash pruritic			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin induration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Renal failure			

subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	4
Myalgia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Muscular weakness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Joint swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	3 / 15 (20.00%)	1 / 11 (9.09%)	2 / 4 (50.00%)
occurrences (all)	4	2	2
Campylobacter colitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Candida infection			

subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemophilus infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	2 / 11 (18.18%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	2 / 11 (18.18%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Vascular device infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	2 / 15 (13.33%)	1 / 11 (9.09%)	2 / 4 (50.00%)
occurrences (all)	2	3	2
Cell death			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			

subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 11 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 11 (9.09%)	0 / 4 (0.00%)
occurrences (all)	1	2	0

Non-serious adverse events	Cohort 4: R/R MZL	Cohort 3: R/R FL	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	21 / 21 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
POEMS syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	6 / 21 (28.57%)	
occurrences (all)	1	7	
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	

Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	4	
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 21 (28.57%)	
occurrences (all)	0	9	
Xerosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Immune system disorders			
Graft versus host disease in skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Graft versus host disease in liver			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Testicular oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	

Bronchiectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Investigations			

Alanine aminotransferase increased				
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)		
occurrences (all)	0	1		
Amylase increased				
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)		
occurrences (all)	0	2		
C-reactive protein increased				
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)		
occurrences (all)	0	1		
Blood glucose increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)		
occurrences (all)	0	0		
Blood creatinine increased				
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)		
occurrences (all)	0	2		
Blood alkaline phosphatase increased				
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)		
occurrences (all)	1	0		
Aspartate aminotransferase increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)		
occurrences (all)	0	0		
Eosinophil count increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)		
occurrences (all)	0	0		
Liver function test abnormal				
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)		
occurrences (all)	0	0		
Lipase increased				
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)		
occurrences (all)	0	2		
Neutrophil count decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)		
occurrences (all)	0	0		
Platelet count decreased				

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Pelvic bone injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	3	
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	3	
Dysgraphia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	2	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Anaemia			

subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Cytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Eosinophilia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Lymphocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	3 / 3 (100.00%)	11 / 21 (52.38%)	
occurrences (all)	3	19	
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	4	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Eyelid ptosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Xerophthalmia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	

Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 21 (19.05%)	
occurrences (all)	0	4	
Colitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	11 / 21 (52.38%)	
occurrences (all)	3	15	
Frequent bowel movements			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Gingival bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	5 / 21 (23.81%)	
occurrences (all)	0	9	
Oesophagitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Retching			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Stomatitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	3	
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Eczema asteatotic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Photosensitivity reaction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	2 / 21 (9.52%)	
occurrences (all)	1	2	
Rash			
subjects affected / exposed	1 / 3 (33.33%)	4 / 21 (19.05%)	
occurrences (all)	1	4	
Rash pruritic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Skin induration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	4	
Arthralgia			

subjects affected / exposed	0 / 3 (0.00%)	5 / 21 (23.81%)	
occurrences (all)	0	5	
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Joint swelling			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 3 (33.33%)	8 / 21 (38.10%)	
occurrences (all)	1	10	
Campylobacter colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Cytomegalovirus infection reactivation			

subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	4	
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Haemophilus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Vascular device infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	4	
Cell death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 21 (23.81%)	
occurrences (all)	0	5	
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	4	
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	

Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 21 (4.76%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 October 2021	The primary purpose of the amendment was to modify the operating characteristics of the internal Data Safety Monitoring Board (iDSMB), update the time interval that must have elapsed before performing the safety follow-up visit, and update the biomarker sample collection. schedule.
13 September 2022	The primary purpose of this amendment was to include sponsor recommendations regarding coronavirus disease 2019 (COVID-19) monitoring and management, to update data privacy requirements in accordance with the European Union (EU) Clinical Trials Regulation directive, and to include revisions made in administrative changes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported