Clinical trial results:
A Phase Ib/II, Open-Label, Multicenter, Randomized, Controlled Study Investigating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Mosunetuzumab (BTCT4465A) In Combination with CHOP or CHP-Polatuzumab Vedotin in Patients with B Cell Non-Hodgkin Lymphoma

Summary

EudraCT number	2018-001039-29
Trial protocol	FR AT ES
Global end of trial date	12 October 2023

Results information

Result version number	v1 (current)
This version publication date	27 October 2024
First version publication date	27 October 2024

Trial information

Trial identification

Sponsor protocol code	GO40515

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03677141
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, 4058
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
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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	23 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to assess safety and tolerability of mosunetuzumab in combination with CHOP and in combination with CHP-pola (Phase Ib), and to compare M-CHP-pola with rituximab in combination with CHP-pola in participants with previously untreated DLBCL (Phase II).

Protection of trial subjects:

Participants were required to sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 October 2018
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: 14
Country: Number of subjects enrolled	Spain: 19
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Korea, Republic of: 13
Country: Number of subjects enrolled	Poland: 4
Country: Number of subjects enrolled	United States: 63
Worldwide total number of subjects	117
EEA total number of subjects	41

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)	51
From 65 to 84 years	65
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Phase Ib: Participants with relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (NHL). Phase II: Participants with previously untreated diffuse large B-cell lymphoma (DLBCL).

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	Group A1: Phase Ib Mosunetuzumab + CHOP

Arm description:

Participants with relapsed/refractory (R/R) B-cell non-Hodgkin lymphoma (NHL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).

Arm type	Experimental
Investigational medicinal product name	Mosunetuzumab
Investigational medicinal product code	
Other name	RO7030816; BTCT4465A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received intravenous (IV) mosunetuzumab on Days 1, 8, and 15 of Cycle 1, and on Day 1 of Cycles 2-6 (cycle length = 21 days). Participants with stable disease (SD) or partial response (PR) at the end of 6 cycles were eligible to receive mosunetuzumab monotherapy for up to 11 additional cycles on Day 1 of each cycle.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV vincristine on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received IV doxorubicin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	RO0452294
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV rituximab on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV cyclophosphamide on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received prednisone once daily by mouth (PO) on Days 1-5 of each cycle for 6 cycles (cycle length = 21 days).

Arm title	Group A2: Phase Ib Mosunetuzumab + CHOP

Arm description:

Participants with relapsed/refractory (R/R) B-cell NHL received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5. Treatment was given for 6 cycles (cycle length = 21 days).

Arm type	Experimental
Investigational medicinal product name	Mosunetuzumab
Investigational medicinal product code	
Other name	RO7030816; BTCT4465A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received intravenous (IV) mosunetuzumab on Days 1, 8, and 15 of Cycle 1, and on Day 1 of Cycles 2-6 (cycle length = 21 days). Participants with stable disease (SD) or partial response (PR) at the end of 6 cycles were eligible to receive mosunetuzumab monotherapy for up to 11 additional cycles on Day 1 of each cycle.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV cyclophosphamide on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

Investigational medicinal product name	Vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV vincristine on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received IV doxorubicin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received prednisone once daily by mouth (PO) on Days 1-5 of each cycle for 6 cycles (cycle length = 21 days).

Arm title	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola

Arm description:

Participants with R/R NHL received 6 cycles of mosunetuzumab (M) + cyclophosphamide, doxorubicin, prednisone (CHP), and polatuzumab vedotin (Pola) (cycle length = 21 days). Participants received M on C1D2, C1D8, and C1D15, C2D2, and on D1 of subsequent cycles if well tolerated. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Arm type	Experimental
Investigational medicinal product name	Mosunetuzumab
Investigational medicinal product code	
Other name	RO7030816; BTCT4465A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV mosunetuzumab on C1D2,C1D8, C1D15, C2D2, and on D1 of subsequent cycles if well tolerated (cycle length = 21 days). Participants with SD or PR at the end of 6 cycles were eligible to receive mosunetuzumab monotherapy for up to 11 additional cycles on on Day 1 of each cycle.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV cyclophosphamide on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	RO5541077
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV polatuzumab vedotin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received IV doxorubicin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received prednisone once daily by mouth (PO) on Days 1-5 of each cycle for 6 cycles (cycle length = 21 days).

Arm title	Group C: Phase II Mosunetuzumab + CHOP

Arm description:

Participants with previously untreated diffuse large B-cell lymphoma (DLBCL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).

Arm type	Experimental
Investigational medicinal product name	Mosunetuzumab
Investigational medicinal product code	
Other name	RO7030816; BTCT4465A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received intravenous (IV) mosunetuzumab on Days 1, 8, and 15 of Cycle 1, and on Day 1 of Cycles 2-6 (cycle length = 21 days). Participants with stable disease (SD) or partial response (PR) at the end of 6 cycles were eligible to receive mosunetuzumab monotherapy for up to 11 additional cycles on Day 1 of each cycle.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV cyclophosphamide on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

Investigational medicinal product name	Vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV vincristine on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received IV doxorubicin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received prednisone once daily by mouth (PO) on Days 1-5 of each cycle for 6 cycles (cycle length = 21 days).

Arm title	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)

Arm description:

Participants received M-CHP-Pola for 6 cycles (cycle length = 21 days). Participants received M on C1D1, C1D8, and C1D15, then on D1 of subsequent cycles. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Arm type	Experimental
Investigational medicinal product name	Mosunetuzumab
Investigational medicinal product code	
Other name	RO7030816; BTCT4465A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV mosunetuzumab on Days 1, 8, and 15 of Cycle 1, then on Day 1 of subsequent cycles (cycle length = 21 days). Participants with SD or PR at the end of 6 cycles were eligible to receive mosunetuzumab monotherapy for up to 11 additional cycles on on Day 1 of each cycle.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV cyclophosphamide on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	RO5541077
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV polatuzumab vedotin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received IV doxorubicin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received prednisone once daily by mouth (PO) on Days 1-5 of each cycle for 6 cycles (cycle length = 21 days).

Arm title	Arm 2: Phase II Rituximab + CHP-Pola (randomized)

Arm description:

Participants received R-CHP-Pola for 6 cycles (cycle length = 21 days). R-CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Arm type	Active comparator

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV cyclophosphamide on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	RO5541077
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV polatuzumab vedotin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received IV doxorubicin on Day 1 of each cycle for 6 cycles (cycle length = 21 days).

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

Dosage and administration details:

Participants received prednisone once daily by mouth (PO) on Days 1-5 of each cycle for 6 cycles (cycle length = 21 days).

Number of subjects in period 1	Group A1: Phase Ib Mosunetuzumab + CHOP	Group A2: Phase Ib Mosunetuzumab + CHOP	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola
Started	3	4	8
Completed	1	3	1
Not completed	2	1	7
Adverse event, serious fatal	2	1	6
Consent withdrawn by subject	-	-	1
Screen failure or enrolled in error	-	-	-
Physician decision	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)
Started	40	40	22

Completed	28	31	19
Not completed	12	9	3
Adverse event, serious fatal	9	5	3
Consent withdrawn by subject	1	1	-
Screen failure or enrolled in error	-	2	-
Physician decision	-	1	-
Lost to follow-up	2	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Group A1: Phase Ib Mosunetuzumab + CHOP
Reporting group description:	
Participants with relapsed/refractory (R/R) B-cell non-Hodgkin lymphoma (NHL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).	
Reporting group title	Group A2: Phase Ib Mosunetuzumab + CHOP
Reporting group description:	
Participants with relapsed/refractory (R/R) B-cell NHL received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5. Treatment was given for 6 cycles (cycle length = 21 days).	
Reporting group title	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola
Reporting group description:	
Participants with R/R NHL received 6 cycles of mosunetuzumab (M) + cyclophosphamide, doxorubicin, prednisone (CHP), and polatuzumab vedotin (Pola) (cycle length = 21 days). Participants received M on C1D2, C1D8, and C1D15, C2D2, and on D1 of subsequent cycles if well tolerated. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).	
Reporting group title	Group C: Phase II Mosunetuzumab + CHOP
Reporting group description:	
Participants with previously untreated diffuse large B-cell lymphoma (DLBCL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).	
Reporting group title	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)
Reporting group description:	
Participants received M-CHP-Pola for 6 cycles (cycle length = 21 days). Participants received M on C1D1, C1D8, and C1D15, then on D1 of subsequent cycles. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).	
Reporting group title	Arm 2: Phase II Rituximab + CHP-Pola (randomized)
Reporting group description:	
Participants received R-CHP-Pola for 6 cycles (cycle length = 21 days). R-CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).	

Reporting group values	Group A1: Phase Ib Mosunetuzumab + CHOP	Group A2: Phase Ib Mosunetuzumab + CHOP	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola
Number of subjects	3	4	8
Age categorical Units: Subjects			
Adults (18-64 years)	1	0	5
From 65-84 years	1	4	3
85 years and over	1	0	0
Age Continuous Units: Years			
arithmetic mean	72.0	71.3	60.1
standard deviation	± 13.0	± 3.4	± 18.0
Sex: Female, Male Units: Participants			
Female	0	1	3
Male	3	3	5

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	4	8
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	3
Not Hispanic or Latino	3	3	5
Unknown or Not Reported	0	0	0

Reporting group values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)
Number of subjects	40	40	22
Age categorical Units: Subjects			
Adults (18-64 years)	19	14	12
From 65-84 years	21	26	10
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	63.4	65.0	57.7
standard deviation	± 11.0	± 10.0	± 14.3
Sex: Female, Male Units: Participants			
Female	18	14	8
Male	22	26	14
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	10	5	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	28	30	20
More than one race	0	0	0
Unknown or Not Reported	2	4	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	2	3
Not Hispanic or Latino	36	35	18
Unknown or Not Reported	1	3	1

Reporting group values	Total		
Number of subjects	117		

Age categorical Units: Subjects			
Adults (18-64 years)	51		
From 65-84 years	65		
85 years and over	1		
Age Continuous Units: Years arithmetic mean standard deviation	 -		
Sex: Female, Male Units: Participants			
Female	44		
Male	73		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1		
Asian	15		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	1		
White	93		
More than one race	0		
Unknown or Not Reported	7		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	12		
Not Hispanic or Latino	100		
Unknown or Not Reported	5		

End points

End points reporting groups

Reporting group title	Group A1: Phase Ib Mosunetuzumab + CHOP

Reporting group description:

Participants with relapsed/refractory (R/R) B-cell non-Hodgkin lymphoma (NHL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).

Reporting group title	Group A2: Phase Ib Mosunetuzumab + CHOP

Reporting group description:

Participants with relapsed/refractory (R/R) B-cell NHL received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5. Treatment was given for 6 cycles (cycle length = 21 days).

Reporting group title	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola

Reporting group description:

Participants with R/R NHL received 6 cycles of mosunetuzumab (M) + cyclophosphamide, doxorubicin, prednisone (CHP), and polatuzumab vedotin (Pola) (cycle length = 21 days). Participants received M on C1D2, C1D8, and C1D15, C2D2, and on D1 of subsequent cycles if well tolerated. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Reporting group title	Group C: Phase II Mosunetuzumab + CHOP

Reporting group description:

Participants with previously untreated diffuse large B-cell lymphoma (DLBCL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).

Reporting group title	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)

Reporting group description:

Participants received M-CHP-Pola for 6 cycles (cycle length = 21 days). Participants received M on C1D1, C1D8, and C1D15, then on D1 of subsequent cycles. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Reporting group title	Arm 2: Phase II Rituximab + CHP-Pola (randomized)

Reporting group description:

Participants received R-CHP-Pola for 6 cycles (cycle length = 21 days). R-CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Primary: Complete response (CR) rate at the time of primary response assessment (PRA) based on positron emission tomography - computed tomography (PET-CT) as determined by independent review committee (IRC)

End point title	Complete response (CR) rate at the time of primary response assessment (PRA) based on positron emission tomography - computed tomography (PET-CT) as determined by independent review committee (IRC)[1]

End point description:

The CR rate was defined as the percentage of participants with CR. Assessments were made according to the Lugano 2014 Response Criteria. The intent-to-treat (ITT) population consisted of all participants. Efficacy analyses for Arms A1, A2, and B were exploratory. The primary efficacy analysis compared Arm 1 vs Arm 2, with participants grouped according to the treatment arm assigned at randomization. Group C was included in secondary efficacy analysis, and efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Primary

End point timeframe:

6-8 weeks after either C6D1 or last dose of study treatment

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory. The primary efficacy analysis compared Arm 1 vs Arm 2, with participants grouped according to the treatment arm assigned at randomization. Group C was included in secondary efficacy analysis.

End point values	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	22		
Units: Percentage of participants				
number (confidence interval 95%)	72.5 (56.11 to 85.40)	77.3 (54.63 to 92.18)		

Statistical analyses

Statistical analysis title	CR rate at PRA by IRC based on PET-CT
Comparison groups	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized) v Arm 2: Phase II Rituximab + CHP-Pola (randomized)
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in rates
Point estimate	-4.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.61
upper limit	21.07

Secondary: CR rate at PRA based on CT only as determined by the investigator (Phase II)

End point title	CR rate at PRA based on CT only as determined by the investigator (Phase II)[2]

End point description:

The intent-to-treat (ITT) population consisted of all participants. Efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Secondary

End point timeframe:

6-8 weeks after either C6D1 or last dose of study treatment

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	22	
Units: Percentage of participants				
number (confidence interval 95%)	50.0 (33.80 to 66.20)	47.5 (31.51 to 63.87)	31.8 (13.86 to 54.87)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall response rate (ORR) at PRA based on PET-CT as determined by the investigator (Phase II)

End point title	Overall response rate (ORR) at PRA based on PET-CT as determined by the investigator (Phase II)[3]

End point description:

ORR is defined as a CR or PR at the time of primary assessment based on PET-CT, as determined by the investigator. The intent-to-treat (ITT) population consisted of all participants. Efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Secondary

End point timeframe:

6-8 weeks after either C6D1 or last dose of study treatment

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	22	
Units: Percentage of participants				
number (confidence interval 95%)				
ORR	87.5 (73.20 to 95.81)	80.0 (64.35 to 90.95)	77.3 (54.63 to 92.18)	

Statistical analyses

No statistical analyses for this end point

Secondary: ORR at PRA based on CT only as determined by the investigator (Phase II)

End point title	ORR at PRA based on CT only as determined by the investigator (Phase II)[4]

End point description:

ORR is defined as a CR or PR at the time of primary assessment based on CT only, as determined by the investigator. The intent-to-treat (ITT) population consisted of all participants. Efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Secondary

End point timeframe:

6-8 weeks after either C6D1 or last dose of study treatment

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	22	
Units: Percentage of participants				
number (confidence interval 95%)	85.0 (70.16 to 94.29)	72.5 (56.11 to 85.40)	81.8 (59.72 to 94.81)	

Statistical analyses

No statistical analyses for this end point

Secondary: Best ORR based on PET-CT and/or CT scan as determined by the investigator (Phase II)

End point title	Best ORR based on PET-CT and/or CT scan as determined by the investigator (Phase II)[5]

End point description:

Best ORR was defined as CR or PR at any time on study and based on PET-CT or CT only as determined by the investigator. The intent-to-treat (ITT) population consisted of all participants. Efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Secondary

End point timeframe:

Up to approximately 50 months

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	36	22	
Units: Percentage of responders				
number (confidence interval 95%)				
Best ORR	95.0 (83.08 to 99.39)	85.0 (70.16 to 94.29)	95.5 (77.16 to 99.88)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival (PFS) as determined by the investigator (Phase II)

End point title	Progression-free survival (PFS) as determined by the investigator (Phase II)[6]

End point description:

PFS is defined as the time from randomization to the first occurrence of disease progression or relapse as determined by the investigator, or death from any cause, whichever occurs first. Efficacy analyses for Arms A1, A2, and B were exploratory. The number of participants analyzed reflects the number of participants with the event. The earliest contributing event to PFS is reported. The range (min-max) values are based on censored observations (participants without a baseline-evaluable tumor assessment were censored at the date of randomization or first study treatment, plus 1 day).

The median values for each arm could not be determined due to an insufficient number of participants with the event. The values in those fields are placeholder values.

End point type	Secondary

End point timeframe:

Up to approximately 50 months

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	22	
Units: Months				
median (full range (min-max))	0 (0 to 31)	0 (0 to 30)	3 (3 to 30)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response (DOR) as determined by the investigator (Phase II)

End point title	Duration of response (DOR) as determined by the investigator (Phase II)[7]

End point description:

DOR is defined as the time from the first occurrence of a documented objective response to disease progression or relapse as determined by the investigator, or death from any cause, whichever occurs first. The number of participants analyzed was the number of participants with a PR or CR in each arm.

The range values (min-max) are based on censored observations (if a participant did not experience disease progression or death prior to the end of the trial DOR was censored on the date of the last tumor assessment).

The median values for each arm could not be determined due to an insufficient number of participants with the event. The values in those fields are placeholder values.

End point type	Secondary

End point timeframe:

Up to approximately 50 months

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38[8]	34[9]	21[10]	
Units: Months				
median (full range (min-max))	0 (0 to 28)	0 (0 to 28)	1 (1 to 27)	

Notes:

[8] - The median could not be determined due to an insufficient number of participants with the event.

[9] - The median could not be determined due to an insufficient number of participants with the event.

[10] - The median could not be determined due to an insufficient number of participants with the event.

Statistical analyses

No statistical analyses for this end point

Secondary: PFS at 1 year as determined by the investigator (Phase II)

End point title	PFS at 1 year as determined by the investigator (Phase II)[11]

End point description:

PFS at 1 year is defined as the proportion of participants with disease progression or relapse as determined by the investigator, or death from any cause within 1 year of randomization. Efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Secondary

End point timeframe:

1 year

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	22	
Units: Percentage of participants				
number (confidence interval 95%)	77.47 (63.65 to 91.29)	70.83 (55.59 to 86.07)	81.82 (65.70 to 97.94)	

Statistical analyses

No statistical analyses for this end point

Secondary: Event-free survival (EFS) as determined by the investigator (Phase II)

End point title	Event-free survival (EFS) as determined by the investigator (Phase II)[12]

End point description:

EFS is defined as the time from randomization to the first occurrence of disease progression or relapse, as determined by the investigator, initiation of new anti-lymphoma therapy (NALT), or death from any cause, whichever occurs first. Efficacy analyses for Arms A1, A2, and B were exploratory. The number of participants analyzed reflects the number of participants with the event. The range values (min-max) are based on censored observations (if a participant did not experience disease progression or death prior to the end of the trial DOR was censored on the date of the last tumor assessment).

The median values for each arm could not be determined due to an insufficient number of participants with the event. The values in those fields are placeholder values.

End point type	Secondary

End point timeframe:

Up to 50 months

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Efficacy analyses for Arms A1, A2, and B were exploratory.

End point values	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	11	5	
Units: Months				
median (full range (min-max))	2 (2 to 31)	0 (0 to 30)	3 (3 to 30)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to deterioration in lymphoma symptoms as measured by the Functional Assessment of Cancer Therapy - Lymphoma (FACT-Lym) subscale

End point title	Time to deterioration in lymphoma symptoms as measured by the Functional Assessment of Cancer Therapy - Lymphoma (FACT-Lym) subscale[13]

End point description:

The intent-to-treat (ITT) population consisted of all participants. Efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Secondary

End point timeframe:

C1D1 through follow-up period (to begin 2 years after PRA or at the time of study drug discontinuation)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was specific to the arms reported.

End point values	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	22		
Units: Months				
median (confidence interval 95%)	9999 (2.3 to 9999)	6.5 (2.1 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to deterioration in physical functioning and fatigue as measured by the European Organization for Research and Treatment of Cancer Quality of Life - Core 30 Questionnaire (EORTC QLQ-C30)

End point title	Time to deterioration in physical functioning and fatigue as measured by the European Organization for Research and Treatment of Cancer Quality of Life - Core 30 Questionnaire (EORTC QLQ-C30)[14]

End point description:

The intent-to-treat (ITT) population consisted of all participants. Efficacy analyses for Arms A1, A2, and B were exploratory.

End point type	Secondary

End point timeframe:

C1D1 through follow-up period (to begin 2 years after PRA or at the time of study drug discontinuation)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was specific to the arms reported.

End point values	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	22		
Units: Months				
median (confidence interval 95%)	2.3 (1.2 to 5.4)	2.3 (0.8 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Polatuzumab Vedotin Serum Concentrations

End point title	Polatuzumab Vedotin Serum Concentrations[15]

End point description:

Participants with at least one pharmacokinetic (PK) sample were included in analysis. Arms in which participants did not receive polatuzumab vedotin were not included in this endpoint.

End point type	Secondary

End point timeframe:

C2D1, C6D1

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was specific to arms assigned to treatment with polatuzumab vedotin.

End point values	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8[16]	40[17]	22[18]	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
C2D1 pre-dose	0.993 (± 779.4)	1.99 (± 80.7)	1.73 (± 107.9)	
C6D1 pre-dose	2.76 (± 820.1)	8.13 (± 34.5)	5.8 (± 42)	

Notes:

[16] - C2D1 n = 6
C6D1 n= 4
[17] - C2D1 n = 33
C6D1 n = 27
[18] - C2D1 n = 18
C6D1 n = 20

Statistical analyses

No statistical analyses for this end point

Secondary: Polatuzumab Vedotin antibody-conjugated monomethyl auristatin E (acMMAE) Serum Concentrations

End point title	Polatuzumab Vedotin antibody-conjugated monomethyl auristatin E (acMMAE) Serum Concentrations[19]

End point description:

Participants with at least one pharmacokinetic (PK) sample were included in analysis. Arms in which participants did not receive polatuzumab vedotin were not included in this endpoint.

999 = No data were collected at that timepoint.

End point type	Secondary

End point timeframe:

C1D1-C6D1

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was specific to arms assigned to treatment with polatuzumab vedotin.

End point values	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8[20]	40[21]	22[22]	
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1 post-dose	620 (± 54.5)	668 (± 21.2)	584 (± 23.1)	
C1D2 pre-dose	219 (± 412.2)	999 (± 999)	999 (± 999)	
C1D2 24hrs post-dose	115 (± 658.3)	275 (± 28.2)	999 (± 999)	
C1D8 pre-dose	23 (± 1040.4)	42 (± 82)	999 (± 999)	
C1D15 pre-dose	8.22 (± 550.4)	13.2 (± 87.4)	999 (± 999)	
C2D1 pre-dose	4.87 (± 626)	6.81 (± 80.1)	7.09 (± 95.5)	
C2D1 post-dose	656 (± 21.1)	653 (± 18)	654 (± 21)	
C3D1 pre-dose	19.2 (± 58.7)	15.8 (± 39.5)	999 (± 999)	
C3D1 post-dose	144 (± 112947.3)	544 (± 90.7)	999 (± 999)	
C4D1 pre-dose	16.8 (± 79.6)	16.8 (± 50.3)	15.6 (± 41.4)	
C4D1 post-dose	783 (± 26.5)	614 (± 15.4)	696 (± 24.1)	
C5D1 pre-dose	7.14 (± 343.5)	19 (± 39.7)	999 (± 999)	
C5D1 post-dose	544 (± 37.6)	605 (± 21.6)	999 (± 999)	
C6D1 pre-dose	11.8 (± 476.6)	21.2 (± 34.7)	17.3 (± 40.8)	

Notes:

[20] - n = 8,7,8,7,7,6,6,5,5,4,4,3,3,4 respectively

[21] - n = 22,0,24,29,30,31,32,33,30,33,30,29,9,25 respectively

[22] - n = 16,0,0,0,0,18,13,0,0,21,18,0,0,19 respectively

Statistical analyses

No statistical analyses for this end point

Secondary: Polatuzumab Vedotin Unconjugated mono-methyl auristatin E (MMAE) Serum Concentrations

End point title	Polatuzumab Vedotin Unconjugated mono-methyl auristatin E (MMAE) Serum Concentrations[23]

End point description:

Participants with at least one pharmacokinetic (PK) sample were included in analysis. Arms in which participants did not receive polatuzumab vedotin were not included in this endpoint.

999 = No data were collected at that timepoint.
9999 = If more than one-third of values were lower than reportable, only the median, maximum, and geometric mean are reported.

End point type	Secondary

End point timeframe:

C1D1-C6D1

Notes:

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

Justification: This endpoint was specific to arms assigned to treatment with polatuzumab vedotin.

End point values	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8[24]	40[25]	22[26]	
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1 post-dose	0.535 (± 464.6)	0.55 (± 71.1)	0.432 (± 78.8)	
C1D2 pre-dose	1.94 (± 114.2)	999 (± 999)	999 (± 999)	
C1D2 24hrs post-dose	3.3 (± 97.8)	2.82 (± 51.9)	999 (± 999)	
C1D8 pre-dose	2.95 (± 80.9)	1.27 (± 93.6)	999 (± 999)	
C1D15 pre-dose	0.604 (± 113.3)	0.301 (± 104.1)	999 (± 999)	
C2D1 pre-dose	0.187 (± 47.3)	0.0773 (± 110.2)	0.0697 (± 87)	
C2D1 post-dose	0.238 (± 64)	0.137 (± 84)	0.116 (± 56.3)	
C3D1 pre-dose	0.168 (± 92)	0.146 (± 96.9)	999 (± 999)	
C3D1 post-dose	0.111 (± 173.9)	0.203 (± 92.7)	999 (± 999)	
C4D1 pre-dose	0.0491 (± 9999)	0.14 (± 93.8)	0.106 (± 88.9)	
C4D1 post-dose	0.0825 (± 188.3)	0.186 (± 66.1)	0.164 (± 43.6)	
C5D1 pre-dose	0.0741 (± 247)	0.137 (± 74.4)	999 (± 999)	
C5D1 post-dose	0.212 (± 54.2)	0.17 (± 38.1)	999 (± 999)	
C6D1 pre-dose	0.0967 (± 194.2)	0.142 (± 63.8)	0.0974 (± 82.4)	

Notes:

[24] - n = 8,7,8,7,7,6,6,5,5,4,4,3,3,4 respectively

[25] - n = 29,0,30,30,30,33,35,33,32,33,30,30,7,27

[26] - n = 16,0,0,0,0,18,14,0,0,21,18,0,0,19 respectively

Statistical analyses

No statistical analyses for this end point

Secondary: Mosunetuzumab Serum Concentrations

End point title	Mosunetuzumab Serum Concentrations[27]

End point description:

Participants with at least one pharmacokinetic (PK) sample were included in analysis. Arms in which participants did not receive mosunetuzumab were not included in this endpoint.

9999 = 0 participants analyzed for this timepoint.

End point type	Secondary

End point timeframe:

C1D1-C5D1

Notes:

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

Justification: This endpoint was specific to arms assigned to treatment with mosunetuzumab.

End point values	Group A1: Phase Ib Mosunetuzumab + CHOP	Group A2: Phase Ib Mosunetuzumab + CHOP	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola	Group C: Phase II Mosunetuzumab + CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[28]	4[29]	8[30]	40[31]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
C1D1 post-dose	0.157 (± 22.1)	0.181 (± 26.7)	9999 (± 9999)	0.155 (± 34.1)
C1D1 2 hrs post-dose	0.152 (± 27.8)	0.163 (± 25.8)	9999 (± 9999)	0.151 (± 28.1)
C1D2 24 hrs post-dose	0.103 (± 23.3)	0.112 (± 8.1)	0.0947 (± 60.2)	0.096 (± 35.7)
C1D8 pre-dose	0.0331 (± 49)	0.0218 (± 153.2)	0.0334 (± 113.6)	0.0253 (± 62.2)
C1D8 post-dose	0.342 (± 18.8)	0.427 (± 36.2)	0.354 (± 36.9)	0.426 (± 30.3)
C1D8 2hrs post-dose	0.32 (± 28.5)	0.409 (± 50.1)	0.349 (± 43.1)	0.388 (± 27.6)
C1D15 pre-dose	0.0866 (± 47.9)	0.0884 (± 52.8)	0.0911 (± 57.7)	0.0953 (± 41.8)
C1D15 post-dose	2.83 (± 22.6)	5.71 (± 38.6)	5.72 (± 44)	7.13 (± 27.7)
C1D15 2 hrs post-dose	2.28 (± 7.5)	5.66 (± 38.7)	5.92 (± 18.5)	6.56 (± 28.4)
C2D1 pre-dose	0.549 (± 24.3)	1.52 (± 49.4)	9999 (± 9999)	1.67 (± 32.1)
C2D1 post-dose	2.86 (± 7.2)	6.75 (± 42.2)	9999 (± 9999)	8.31 (± 27.4)
C2D1 2 hrs post-dose	2.38 (± 1.2)	7.33 (± 44.7)	7.65 (± 35.1)	8.28 (± 26.7)
C2D2 pre-dose	9999 (± 9999)	9999 (± 9999)	1.37 (± 38.6)	9999 (± 9999)
C2D2 post-dose	9999 (± 9999)	9999 (± 9999)	8.9 (± 34.1)	9999 (± 9999)
C3D1 pre-dose	0.458 (± 36.3)	1.08 (± 53.3)	1.21 (± 45.1)	1.11 (± 30.2)
C3D1 post-dose	3.37 (± 23.4)	7.19 (± 30.8)	6.66 (± 41.3)	7.3 (± 39.2)
C4D1 pre-dose	0.502 (± 36.9)	1.09 (± 44.4)	0.782 (± 90)	1.03 (± 33.9)
C4D1 post-dose	3.24 (± 31.3)	7.38 (± 26.3)	4.09 (± 83)	7.41 (± 44)
C5D1 pre-dose	0.426 (± 51.7)	1.02 (± 62)	0.33 (± 176.6)	1.12 (± 31.6)
C1D2 2 hrs post-dose	9999 (± 9999)	9999 (± 9999)	0.145 (± 80)	9999 (± 9999)

Notes:

[28] - C1D15 2hrs post-dose - C2D1 2hrs post-dose n = 2

[29] - C1D8 n = n = 3

[30] - n = 0, 0, 8, 7, 7, 7, 7, 7, 7, 0, 0, 6, 6, 5, 5, 5, 4, 4, 3, 7 respectively

[31] - n = 37, 35, 36, 39, 39, 38, 39, 39, 38, 37, 35, 34, 0, 0, 33, 34, 32, 32, 30, 0 respectively

End point values	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)			
Subject group type	Reporting group			
Number of subjects analysed	40[32]			
Units: ug/mL				
geometric mean (geometric coefficient				

of variation)				
C1D1 post-dose	0.132 (± 73.2)			
C1D1 2 hrs post-dose	9999 (± 9999)			
C1D2 24 hrs post-dose	0.0825 (± 46.1)			
C1D8 pre-dose	0.0263 (± 77)			
C1D8 post-dose	0.376 (± 38.8)			
C1D8 2hrs post-dose	9999 (± 9999)			
C1D15 pre-dose	0.102 (± 47.7)			
C1D15 post-dose	6.31 (± 34.8)			
C1D15 2 hrs post-dose	9999 (± 9999)			
C2D1 pre-dose	1.46 (± 62.8)			
C2D1 post-dose	7.69 (± 38.3)			
C2D1 2 hrs post-dose	9999 (± 9999)			
C2D2 pre-dose	9999 (± 9999)			
C2D2 post-dose	9999 (± 9999)			
C3D1 pre-dose	0.885 (± 43)			
C3D1 post-dose	6.76 (± 28.9)			
C4D1 pre-dose	0.932 (± 52)			
C4D1 post-dose	5.55 (± 80.3)			
C5D1 pre-dose	0.935 (± 106.1)			
C1D2 2 hrs post-dose	9999 (± 9999)			

Notes:

[32] - n = 22, 0, 29, 35, 35, 0, 31, 31, 0, 33, 30, 0, 0, 0, 8, 26, 32, 28, 4, 0 respectively

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline prevalence and incidence of treatment emergent anti-drug antibodies (ADA) to Mosunetuzumab

End point title	Baseline prevalence and incidence of treatment emergent anti-drug antibodies (ADA) to Mosunetuzumab[33]

End point description:

Participants are considered to have treatment-induced ADA responses if they are ADA negative or missing data at baseline and then develop an ADA response following study drug administration. Participants are considered to have treatment-enhanced ADA responses if they are ADA positive at baseline and the titer of one or more post baseline samples is at least 4-fold greater than the titer of the baseline sample. Patients are considered to be negative for ADAs if they are ADA negative at all timepoints or if they are ADA positive at baseline but do not have any post-baseline samples with a titer that is at least 4-fold greater than the titer of the baseline sample (treatment unaffected). The immunogenicity analysis population included all participants with at least one ADA assessment. The number of participants analyzed are the values for baseline-evaluable participants and post-baseline evaluable participants.

End point type	Secondary

End point timeframe:

Cycles 1, 2, 6, 16, and at early discontinuation visit or at PRA (6-8 weeks after either C6D1 or last dose of study treatment)

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was specific to arms assigned to treatment with mosunetuzumab.

End point values	Group A1: Phase Ib Mosunetuzumab + CHOP	Group A2: Phase Ib Mosunetuzumab + CHOP	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola	Group C: Phase II Mosunetuzumab + CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	8[34]	40[35]
Units: Number of participants				
Positive sample at baseline	0	0	0	0
Not positive at baseline	3	4	8	38
Positive for treatment-emergent ADA	0	0	0	0
Positive for treatment-induced ADA	0	0	0	0
Positive for treatment-enhanced ADA	0	0	0	0
Negative for treatment-emergent ADA	3	4	6	39

Notes:

[34] - n = 8, 8, 6, 6, 6, 6 respectively

[35] - n = 38, 38, 39, 39, 39, 39 respectively

End point values	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)			
Subject group type	Reporting group			
Number of subjects analysed	38[36]			
Units: Number of participants				
Positive sample at baseline	0			
Not positive at baseline	33			
Positive for treatment-emergent ADA	0			
Positive for treatment-induced ADA	0			
Positive for treatment-enhanced ADA	0			
Negative for treatment-emergent ADA	37			

Notes:

[36] - n = 33, 33, 37, 37, 37, 37 respectively

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline prevalence and incidence of treatment emergent ADA to Polatuzumab Vedotin

End point title	Baseline prevalence and incidence of treatment emergent ADA to Polatuzumab Vedotin[37]

End point description:

Participants are considered to have treatment-induced ADA responses if they are ADA negative or missing data at baseline and then develop an ADA response following study drug administration. Participants are considered to have treatment-enhanced ADA responses if they are ADA positive at baseline and the titer of one or more post baseline samples is at least 4-fold greater than the titer of the baseline sample. Patients are considered to be negative for ADAs if they are ADA negative at all timepoints or if they are ADA positive at baseline but do not have any post-baseline samples with a titer that is at least 4-fold greater than the titer of the baseline sample (treatment unaffected). The immunogenicity analysis population included all participants with at least one ADA assessment. The number of participants analyzed are the values for baseline-evaluable participants and post-baseline evaluable participants.

End point type	Secondary

End point timeframe:

Cycles 1, 2, 6, and at early discontinuation visit or at PRA (6-8 weeks after either C6D1 or last dose of study treatment)

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was specific to arms assigned to treatment with polatuzumab vedotin.

End point values	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8[38]	38[39]	22[40]	
Units: Number of participants				
Positive sample at baseline	0	1	2	
Not positive at baseline	8	32	19	
Positive for treatment-emergent ADA	0	0	1	
Positive for treatment-induced ADA	0	0	1	
Positive for treatment-enhanced ADA	0	0	0	
Negative for treatment-emergent ADA	6	37	20	

Notes:

[38] - n = 8, 8, 6, 6, 6, 6 respectively

[39] - n = 38, 38, 37, 37, 37, 37 respectively

[40] - n = 21 for each row

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 30 months

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v26.1

Reporting groups

Reporting group title	Group A1: Phase Ib Mosunetuzumab + CHOP

Reporting group description:

Participants with relapsed/refractory (R/R) B-cell non-Hodgkin lymphoma (NHL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).

Reporting group title	Group A2: Phase Ib Mosunetuzumab + CHOP

Reporting group description:

Participants with relapsed/refractory (R/R) B-cell NHL received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5. Treatment was given for 6 cycles (cycle length = 21 days).

Reporting group title	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola

Reporting group description:

Participants with R/R NHL received 6 cycles of mosunetuzumab (M) + cyclophosphamide, doxorubicin, prednisone (CHP), and polatuzumab vedotin (Pola) (cycle length = 21 days). Participants received M on C1D2, C1D8, C1D15, C2D2, and on D1 of subsequent cycles if well tolerated. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Reporting group title	Group C: Phase II Mosunetuzumab + CHOP

Reporting group description:

Participants with previously untreated diffuse large B-cell lymphoma (DLBCL) received mosunetuzumab on Cycle 1 Day 1 (C1D1), C1D8, and C1D15, then on Day 1 of subsequent cycles. In addition, participants received cyclophosphamide, doxorubicin, and vincristine on D1, and prednisone on D1-D5 (CHOP). Treatment was given for 6 cycles (cycle length = 21 days).

Reporting group title	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)

Reporting group description:

Participants received M-CHP-Pola for 6 cycles (cycle length = 21 days). Participants received M on C1D1, C1D8, and C1D15, then on D1 of subsequent cycles. CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Reporting group title	Arm 2: Phase II Rituximab + CHP-Pola (randomized)

Reporting group description:

Participants received R-CHP-Pola for 6 cycles (cycle length = 21 days). R-CHP-pola was given on D1 of each cycle (D1-D5 for prednisone).

Serious adverse events	Group A1: Phase Ib Mosunetuzumab + CHOP	Group A2: Phase Ib Mosunetuzumab + CHOP	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	6 / 8 (75.00%)
number of deaths (all causes)	2	1	6
number of deaths resulting from adverse events	2	0	4

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Central nervous system lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Aortic rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic leak			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Congestive hepatopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 40 (50.00%)	24 / 38 (63.16%)	3 / 22 (13.64%)
number of deaths (all causes)	9	5	3
number of deaths resulting from adverse events	2	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Central nervous system lymphoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic rupture			

subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Hypotension			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
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			
Chest pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Fatigue			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Death			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer			

subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 40 (0.00%)	5 / 38 (13.16%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	5 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Pulmonary embolism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory failure			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Troponin I increased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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			
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Anastomotic ulcer			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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
Anastomotic leak			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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			
Cardiac failure			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Angina unstable			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Cardiac tamponade			

subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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
Coma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Headache			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Encephalopathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Hepatic encephalopathy			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated neurotoxicity syndrome			

subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Lethargy			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Syncope			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 40 (2.50%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	6 / 40 (15.00%)	5 / 38 (13.16%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	7 / 7	5 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	3 / 40 (7.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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
Colitis			

subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Diarrhoea			
subjects affected / exposed	1 / 40 (2.50%)	3 / 38 (7.89%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Hepatobiliary disorders			
Congestive hepatopathy			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Hypertransaminasaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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 obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Fistula			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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
Enterocolitis infectious			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal oesophagitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
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 norovirus			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 40 (2.50%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Infection			
subjects affected / exposed	0 / 40 (0.00%)	3 / 38 (7.89%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
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	3 / 40 (7.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Urinary tract infection			

subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (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
Dehydration			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (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
Failure to thrive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Group A1: Phase Ib Mosunetuzumab + CHOP	Group A2: Phase Ib Mosunetuzumab + CHOP	Group B: Phase Ib Mosunetuzumab + M-CHP-Pola
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour flare			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vascular disorders			

Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	2	1	1
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Superficial vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pallor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	5 / 8 (62.50%)
occurrences (all)	1	2	5
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	3 / 8 (37.50%)
occurrences (all)	0	1	6
Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Oedema peripheral			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	2 / 8 (25.00%)
occurrences (all)	3	2	3
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Epistaxis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Platelet count decreased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	4	11	1
Serum ferritin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
White blood cell count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Vascular access site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Vascular access site haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vascular access complication			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin laceration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Febrile nonhaemolytic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	2 / 3 (66.67%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	5
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Left ventricular dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Supraventricular tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	4
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Ageusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Facial paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	3 / 8 (37.50%)
occurrences (all)	0	2	3
Horner's syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lacunar infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	2 / 3 (66.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0

Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	2 / 8 (25.00%)
occurrences (all)	5	4	4
Thrombocytopenia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	3 / 8 (37.50%)
occurrences (all)	20	1	11
Splenomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Neutropenia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	4 / 8 (50.00%)
occurrences (all)	1	0	6
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Halo vision			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Retinopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Colonic haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	2
Anal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	3	1	2
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	3 / 8 (37.50%)
occurrences (all)	0	2	3
Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Oral pain			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	6 / 8 (75.00%)
occurrences (all)	1	1	7
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Stomatitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	3 / 8 (37.50%)
occurrences (all)	2	0	4
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Dry skin			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Nail disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Night sweats			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Urticaria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	3
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	3
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Infections and infestations			

Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Skin candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Influenza			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	4 / 8 (50.00%)
occurrences (all)	2	4	4
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	5 / 8 (62.50%)
occurrences (all)	2	1	8
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	3	1	2
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	5 / 8 (62.50%)
occurrences (all)	1	3	13

Non-serious adverse events	Group C: Phase II Mosunetuzumab + CHOP	Arm 1: Phase II Mosunetuzumab + CHP-Pola (randomized)	Arm 2: Phase II Rituximab + CHP-Pola (randomized)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 40 (100.00%)	38 / 38 (100.00%)	22 / 22 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour flare			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Jugular vein thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0

Hypertension			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	1 / 22 (4.55%)
occurrences (all)	0	5	1
Hypotension			
subjects affected / exposed	9 / 40 (22.50%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	13	2	0
Orthostatic hypotension			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Pallor			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	5 / 40 (12.50%)	1 / 38 (2.63%)	1 / 22 (4.55%)
occurrences (all)	5	2	1
Chest pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Chest discomfort			
subjects affected / exposed	3 / 40 (7.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
Asthenia			
subjects affected / exposed	0 / 40 (0.00%)	3 / 38 (7.89%)	1 / 22 (4.55%)
occurrences (all)	0	3	1
Fatigue			
subjects affected / exposed	19 / 40 (47.50%)	12 / 38 (31.58%)	10 / 22 (45.45%)
occurrences (all)	23	13	13
Generalised oedema			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Injection site pain			

subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	1
Pyrexia			
subjects affected / exposed	8 / 40 (20.00%)	4 / 38 (10.53%)	0 / 22 (0.00%)
occurrences (all)	13	4	0
Pain			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	1 / 22 (4.55%)
occurrences (all)	1	1	1
Oedema peripheral			
subjects affected / exposed	8 / 40 (20.00%)	5 / 38 (13.16%)	0 / 22 (0.00%)
occurrences (all)	9	7	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	24 / 40 (60.00%)	22 / 38 (57.89%)	0 / 22 (0.00%)
occurrences (all)	30	27	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	7 / 40 (17.50%)	4 / 38 (10.53%)	3 / 22 (13.64%)
occurrences (all)	7	4	3
Cough			
subjects affected / exposed	7 / 40 (17.50%)	0 / 38 (0.00%)	3 / 22 (13.64%)
occurrences (all)	9	0	3
Epistaxis			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	2 / 22 (9.09%)
occurrences (all)	3	0	3
Hiccups			
subjects affected / exposed	3 / 40 (7.50%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	3	0	1
Nasal congestion			

subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	3 / 40 (7.50%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	3	0	1
Pleural effusion			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 40 (2.50%)	2 / 38 (5.26%)	2 / 22 (9.09%)
occurrences (all)	1	3	2
Productive cough			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Confusional state			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	6 / 40 (15.00%)	2 / 38 (5.26%)	6 / 22 (27.27%)
occurrences (all)	6	2	6
Restlessness			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	0	1	0

Depression			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Alanine aminotransferase increased			
subjects affected / exposed	6 / 40 (15.00%)	10 / 38 (26.32%)	4 / 22 (18.18%)
occurrences (all)	8	10	4
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 40 (12.50%)	6 / 38 (15.79%)	3 / 22 (13.64%)
occurrences (all)	7	6	3
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 40 (7.50%)	1 / 38 (2.63%)	3 / 22 (13.64%)
occurrences (all)	4	1	3
Liver function test increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	2 / 22 (9.09%)
occurrences (all)	3	2	6
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
International normalised ratio increased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	3 / 22 (13.64%)
occurrences (all)	0	1	3
Blood bilirubin increased			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	1	1	0

Lymphocyte count decreased			
subjects affected / exposed	4 / 40 (10.00%)	1 / 38 (2.63%)	3 / 22 (13.64%)
occurrences (all)	19	3	8
Neutrophil count decreased			
subjects affected / exposed	8 / 40 (20.00%)	11 / 38 (28.95%)	5 / 22 (22.73%)
occurrences (all)	13	18	7
Platelet count decreased			
subjects affected / exposed	5 / 40 (12.50%)	4 / 38 (10.53%)	3 / 22 (13.64%)
occurrences (all)	12	8	4
Serum ferritin increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	4 / 40 (10.00%)	4 / 38 (10.53%)	1 / 22 (4.55%)
occurrences (all)	4	4	1
White blood cell count decreased			
subjects affected / exposed	3 / 40 (7.50%)	6 / 38 (15.79%)	3 / 22 (13.64%)
occurrences (all)	10	12	7
Injury, poisoning and procedural complications			
Vascular access site pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular access site haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			

subjects affected / exposed	2 / 40 (5.00%)	9 / 38 (23.68%)	2 / 22 (9.09%)
occurrences (all)	2	10	3
Febrile nonhaemolytic transfusion reaction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Atrial flutter			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	5 / 40 (12.50%)	3 / 38 (7.89%)	2 / 22 (9.09%)
occurrences (all)	6	3	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	9 / 40 (22.50%)	6 / 38 (15.79%)	0 / 22 (0.00%)
occurrences (all)	9	6	0
Ageusia			

subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	7 / 40 (17.50%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	7	2	0
Encephalopathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	9 / 40 (22.50%)	2 / 38 (5.26%)	7 / 22 (31.82%)
occurrences (all)	14	2	8
Horner's syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 40 (2.50%)	5 / 38 (13.16%)	4 / 22 (18.18%)
occurrences (all)	3	6	4
Lacunar infarction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	13 / 40 (32.50%)	3 / 38 (7.89%)	4 / 22 (18.18%)
occurrences (all)	13	3	5
Paraesthesia			
subjects affected / exposed	1 / 40 (2.50%)	2 / 38 (5.26%)	2 / 22 (9.09%)
occurrences (all)	3	2	2
Hypoaesthesia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Taste disorder			

subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Tremor			
subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	1 / 40 (2.50%)	3 / 38 (7.89%)	1 / 22 (4.55%)
occurrences (all)	1	7	2
Leukocytosis			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Febrile neutropenia			
subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
Anaemia			
subjects affected / exposed	17 / 40 (42.50%)	9 / 38 (23.68%)	5 / 22 (22.73%)
occurrences (all)	35	13	11
Thrombocytopenia			
subjects affected / exposed	5 / 40 (12.50%)	6 / 38 (15.79%)	1 / 22 (4.55%)
occurrences (all)	6	10	1
Splenomegaly			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Neutropenia			
subjects affected / exposed	19 / 40 (47.50%)	14 / 38 (36.84%)	7 / 22 (31.82%)
occurrences (all)	30	24	11
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
Eye disorders			

Dry eye			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Halo vision			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	2 / 40 (5.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	2	2	0
Gastrointestinal disorders			
Colonic haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	8 / 40 (20.00%)	6 / 38 (15.79%)	1 / 22 (4.55%)
occurrences (all)	9	6	1
Anal incontinence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	4 / 40 (10.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
Dyspepsia			
subjects affected / exposed	2 / 40 (5.00%)	6 / 38 (15.79%)	0 / 22 (0.00%)
occurrences (all)	3	7	0
Dry mouth			

subjects affected / exposed	6 / 40 (15.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	7	0	1
Diarrhoea			
subjects affected / exposed	12 / 40 (30.00%)	12 / 38 (31.58%)	4 / 22 (18.18%)
occurrences (all)	14	17	6
Constipation			
subjects affected / exposed	14 / 40 (35.00%)	6 / 38 (15.79%)	4 / 22 (18.18%)
occurrences (all)	17	6	4
Lip dry			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Haemorrhoids			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Small intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	22 / 40 (55.00%)	17 / 38 (44.74%)	9 / 22 (40.91%)
occurrences (all)	33	24	10
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	6 / 40 (15.00%)	3 / 38 (7.89%)	2 / 22 (9.09%)
occurrences (all)	9	3	2
Vomiting			
subjects affected / exposed	11 / 40 (27.50%)	9 / 38 (23.68%)	5 / 22 (22.73%)
occurrences (all)	18	11	7
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	12 / 40 (30.00%)	7 / 38 (18.42%)	9 / 22 (40.91%)
occurrences (all)	12	7	9
Dry skin			
subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	1 / 22 (4.55%)
occurrences (all)	3	1	1
Ecchymosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	2 / 40 (5.00%)	4 / 38 (10.53%)	1 / 22 (4.55%)
occurrences (all)	2	4	1
Rash			

subjects affected / exposed	4 / 40 (10.00%)	6 / 38 (15.79%)	4 / 22 (18.18%)
occurrences (all)	5	8	4
Rash maculo-papular			
subjects affected / exposed	2 / 40 (5.00%)	2 / 38 (5.26%)	1 / 22 (4.55%)
occurrences (all)	2	2	1
Urticaria			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Skin hyperpigmentation			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Acute kidney injury			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Dysuria			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	2 / 22 (9.09%)
occurrences (all)	0	2	2
Haematuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	1 / 40 (2.50%)	2 / 38 (5.26%)	1 / 22 (4.55%)
occurrences (all)	1	2	1
Urinary incontinence			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Proteinuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 40 (7.50%)	2 / 38 (5.26%)	1 / 22 (4.55%)
occurrences (all)	3	2	2
Arthritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	3 / 40 (7.50%)	5 / 38 (13.16%)	3 / 22 (13.64%)
occurrences (all)	3	5	3
Muscle spasms			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	3
Muscular weakness			
subjects affected / exposed	1 / 40 (2.50%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	4 / 40 (10.00%)	1 / 38 (2.63%)	3 / 22 (13.64%)
occurrences (all)	4	1	3
Pain in extremity			
subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	1 / 22 (4.55%)
occurrences (all)	2	1	2
Neck pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Infections and infestations			
Bacteraemia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Candida infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Skin candida			

subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Oral candidiasis			
subjects affected / exposed	3 / 40 (7.50%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	3	0	1
Influenza			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	4 / 40 (10.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	4	1	0
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	1
Urinary tract infection			
subjects affected / exposed	1 / 40 (2.50%)	3 / 38 (7.89%)	1 / 22 (4.55%)
occurrences (all)	2	4	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	15 / 40 (37.50%)	11 / 38 (28.95%)	1 / 22 (4.55%)
occurrences (all)	17	13	1

Dehydration			
subjects affected / exposed	4 / 40 (10.00%)	2 / 38 (5.26%)	0 / 22 (0.00%)
occurrences (all)	4	2	0
Hyperglycaemia			
subjects affected / exposed	4 / 40 (10.00%)	2 / 38 (5.26%)	3 / 22 (13.64%)
occurrences (all)	5	3	4
Hyperkalaemia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Hypernatraemia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	1 / 40 (2.50%)	2 / 38 (5.26%)	1 / 22 (4.55%)
occurrences (all)	1	2	1
Hypervolaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	6 / 40 (15.00%)	2 / 38 (5.26%)	1 / 22 (4.55%)
occurrences (all)	14	4	1
Hypocalcaemia			
subjects affected / exposed	6 / 40 (15.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	8	1	0
Hypomagnesaemia			
subjects affected / exposed	6 / 40 (15.00%)	4 / 38 (10.53%)	0 / 22 (0.00%)
occurrences (all)	6	5	0
Hyponatraemia			
subjects affected / exposed	2 / 40 (5.00%)	3 / 38 (7.89%)	2 / 22 (9.09%)
occurrences (all)	9	3	2
Hypophosphataemia			
subjects affected / exposed	7 / 40 (17.50%)	4 / 38 (10.53%)	1 / 22 (4.55%)
occurrences (all)	12	6	1

Metabolic acidosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	13 / 40 (32.50%)	4 / 38 (10.53%)	1 / 22 (4.55%)
occurrences (all)	25	4	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 August 2018	Replaced Pola-M-CHP in first-line DLBCL with a safety run-in group of M-CHOP in first-line DLBCL. ADA objectives added to secondary objectives.
27 October 2018	Updated starting test dose for Group A. Updated inclusion criteria.
27 May 2020	Updates to eligibility criteria.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported