Clinical trial results:
A Phase Ib/II Study Evaluating the Safety, Tolerability and Anti-Tumor Activity of Polatuzumab Vedotin in Combination with Rituximab (R) Or Obinutuzumab (G) Plus Bendamustine (B) In Relapsed or Refractory Follicular or Diffuse Large B-Cell Lymphoma

Summary

EudraCT number	2014-001361-28
Trial protocol	CZ HU DE GB ES NL FR IT
Global end of trial date	21 October 2021

Results information

Result version number	v1 (current)
This version publication date	03 November 2022
First version publication date	03 November 2022

Trial information

Trial identification

Sponsor protocol code	GO29365

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02257567
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hoffmann-La Roche
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland,
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, + 41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, + 41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 October 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was a multicentre, open-label study of polatuzumab vedotin (Pola) administered by intravenous (IV) infusion in combination with standard doses of bendamustine (B) and rituximab (R) or obinutuzumab (G) in participants with relapsed or refractory follicular lymphoma (FL) or diffuse large B-cell lymphoma (DLBCL). The study comprised two stages: a Phase Ib safety run-in stage and a Phase II stage.

Protection of trial subjects:

All participants were required to sign the informed consent form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 October 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	7 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 29
Country: Number of subjects enrolled	Canada: 44
Country: Number of subjects enrolled	Czechia: 20
Country: Number of subjects enrolled	France: 26
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Hungary: 14
Country: Number of subjects enrolled	Italy: 11
Country: Number of subjects enrolled	Korea, Republic of: 20
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Spain: 32
Country: Number of subjects enrolled	Turkey: 19
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	United States: 95
Worldwide total number of subjects	331
EEA total number of subjects	107

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)	133
From 65 to 84 years	191
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

A total of 331 were enrolled in this study at 56 investigative sites in the following countries: Australia, Canada, Czech Republic, France, Germany, Hungary, Italy, Korea, the Netherlands, Spain, Turkey, United Kingdom, and the United States from 15 October 2014 to 20 October 2021.

Pre-assignment

Screening details:

Participants were enrolled in Phase Ib and Phase II to receive polatuzumab vedotin (liquid formulation in randomised & expansion stages; lyophilized in new formulation (NF) cohorts) in combination with standard doses of BG and BR. Out of 331 participants, 327 participants received at least one dose of study drug and their intended treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL

Arm description:

Participants with FL received pola, 1.8 milligrams per kilogram (mg/kg), as intravenous (IV) infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 milligrams per meter-squared (mg/m^2), as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

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

Dosage and administration details:

Rituximab, 375 mg/m^2, administered as IV on Day 1 of each cycle for up to 6 cycles.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL

Arm description:

Participants with DLBCL received pola 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine, 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

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

Dosage and administration details:

Rituximab, 375 mg/m^2, administered as IV on Day 1 of each cycle for up to 6 cycles.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL

Arm description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	GA101; Gazyva; Gazyvaro
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Obinutuzumab, 1000 mg, administered as IV on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

Arm title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL

Arm description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	GA101; Gazyva; Gazyvaro
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Obinutuzumab, 1000 mg, administered as IV on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Arm A (Phase II Randomisation): Pola+BR in FL

Arm description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

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

Dosage and administration details:

Rituximab, 375 mg/m^2, administered as IV on Day 1 of each cycle for up to 6 cycles.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Arm B (Phase II Randomisation): BR in FL

Arm description:

Participants with FL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 28 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Arm type	Active comparator
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	Rituxan; MabThera
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab, 375 mg/m^2, administered as IV on Day 1 of each cycle for up to 6 cycles.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Arm C (Phase II Randomisation): Pola+BR in DLBCL

Arm description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

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

Dosage and administration details:

Rituximab, 375 mg/m^2, administered as IV on Day 1 of each cycle for up to 6 cycles.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Arm D (Phase II Randomisation): BR in DLBCL

Arm description:

Participants with DLBCL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 21 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Arm type	Active comparator
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	Rituxan; MabThera
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab , 375 mg/m^2, administered as IV on Day 1 of each cycle for up to 6 cycles.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Arm E (Phase II Expansion): Pola+BG in FL

Arm description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	GA101; Gazyva; Gazyvaro
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Obinutuzumab, 1000 mg, administered as IV on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Arm title	Arm F (Phase II Expansion): Pola+BG in DLBCL

Arm description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	GA101; Gazyva; Gazyvaro
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Obinutuzumab, 1000 mg, administered as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6.

Arm title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL

Arm description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	
Other name	DCDS4501A
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pola 1.8 mg/kg, administered as IV infusion on Day 2 of Cycle 1, and thereafter on Day 1 of Cycles 2 to 6.

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

Dosage and administration details:

Rituximab, 375 mg/m^2, administered as IV on Day 1 of each cycle for up to 6 cycles.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda; Ribomustin; Levact
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 90 mg/m^2, per day administered as IV on Days 2 and 3 of Cycle 1, then on Days 1 and 2 of Cycle 2 to 6.

Number of subjects in period 1	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL
Started	6	6	6
Safety Population	6	6	6
Completed	4	4	2
Not completed	2	2	4
Adverse event, serious fatal	2	2	2
Consent withdrawn by subject	-	-	2
Physician decision	-	-	-
Not treated/Didn'tContinue	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL
Started	6	39	41
Safety Population	6	38	41
Completed	1	20	22
Not completed	5	19	19
Adverse event, serious fatal	4	15	11

Consent withdrawn by subject	-	-	6
Physician decision	-	-	-
Not treated/Didn'tContinue	-	1	-
Adverse event, non-fatal	1	1	-
Lost to follow-up	-	2	2

Number of subjects in period 1	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL
Started	40	40	20
Safety Population	39	39	20
Completed	6	2	16
Not completed	34	38	4
Adverse event, serious fatal	26	30	2
Consent withdrawn by subject	6	6	1
Physician decision	-	2	-
Not treated/Didn'tContinue	2	-	-
Adverse event, non-fatal	-	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Started	21	106
Safety Population	20	106
Completed	0	30
Not completed	21	76
Adverse event, serious fatal	18	65
Consent withdrawn by subject	1	10
Physician decision	1	-
Not treated/Didn'tContinue	-	-
Adverse event, non-fatal	-	-
Lost to follow-up	1	1

Reporting groups

Reporting group title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL

Reporting group description:

Participants with FL received pola, 1.8 milligrams per kilogram (mg/kg), as intravenous (IV) infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 milligrams per meter-squared (mg/m^2), as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine, 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm A (Phase II Randomisation): Pola+BR in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Arm B (Phase II Randomisation): BR in FL

Reporting group description:

Participants with FL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 28 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Reporting group title	Arm C (Phase II Randomisation): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Arm D (Phase II Randomisation): BR in DLBCL

Reporting group description:

Participants with DLBCL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 21 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Reporting group title	Arm E (Phase II Expansion): Pola+BG in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm F (Phase II Expansion): Pola+BG in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL
Number of subjects	6	6	6
Age categorical Units: Subjects			
Age Continuous Units: years			
median	68.0	65.0	63.5
full range (min-max)	54 to 73	58 to 79	42 to 73
Sex: Female, Male Units: Participants			
Female	4	2	2
Male	2	4	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	5	5	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	6	6
Not Stated	0	0	0
Unknown	0	0	0

Reporting group values	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL
Number of subjects	6	39	41
Age categorical Units: Subjects			

Age Continuous Units: years			
median	71.0	65.0	63.0
full range (min-max)	53 to 84	37 to 74	39 to 80
Sex: Female, Male Units: Participants			
Female	1	18	23
Male	5	21	18
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	6	33	33
More than one race	0	0	0
Unknown or Not Reported	0	4	6
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	1	3
Not Hispanic or Latino	6	34	34
Not Stated	0	2	3
Unknown	0	2	1

Reporting group values	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL
Number of subjects	40	40	20
Age categorical Units: Subjects			

Age Continuous Units: years			
median	67.0	71.0	60.5
full range (min-max)	33 to 86	30 to 84	37 to 86
Sex: Female, Male Units: Participants			
Female	12	15	10
Male	28	25	10
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	6	4	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	0	2
White	26	31	16
More than one race	0	0	0
Unknown or Not Reported	5	4	1
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	1	3

Not Hispanic or Latino	35	36	16
Not Stated	3	1	0
Unknown	1	2	1

Reporting group values	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	Total
Number of subjects	21	106	331
Age categorical Units: Subjects			
Age Continuous Units: years			
median	65.0	70.0	
full range (min-max)	26 to 86	24 to 94	-
Sex: Female, Male Units: Participants			
Female	10	54	151
Male	11	52	180
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	6	8	30
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	7
White	15	83	259
More than one race	0	0	0
Unknown or Not Reported	0	14	34
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	2	3	14
Not Hispanic or Latino	19	87	285
Not Stated	0	13	22
Unknown	0	3	10

End points reporting groups

Reporting group title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL

Reporting group description:

Participants with FL received pola, 1.8 milligrams per kilogram (mg/kg), as intravenous (IV) infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 milligrams per meter-squared (mg/m^2), as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine, 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm A (Phase II Randomisation): Pola+BR in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Arm B (Phase II Randomisation): BR in FL

Reporting group description:

Participants with FL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 28 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Reporting group title	Arm C (Phase II Randomisation): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Arm D (Phase II Randomisation): BR in DLBCL

Reporting group description:

Participants with DLBCL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 21 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Reporting group title	Arm E (Phase II Expansion): Pola+BG in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm F (Phase II Expansion): Pola+BG in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm H (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm H (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of

Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Subject analysis set title	Arm G (Phase II NF Cohort): Pola+BR in DLBCL
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Primary: Phase Ib: Percentage of Participants with Adverse Events (AEs)

End point title	Phase Ib: Percentage of Participants with Adverse Events

End point description:

An AE is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events. AEs were reported based on the National Cancer Institute Common Terminology Criteria for AEs, version 4.0 (NCI-CTCAE, v4.0). Safety population consisted of all ITT participants in Phase Ib who received at least one dose of study medication.

End point type	Primary

End point timeframe:

From the study start up to the end of the study (up to approximately 84 months)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: percentage of participants				
number (not applicable)	100	100	100	100

Statistical analyses

No statistical analyses for this end point

Primary: Arm G+H (Phase II NF Cohort): Percentage of Participants with AEs

End point title	Arm G+H (Phase II NF Cohort): Percentage of Participants with AEs[3][4]

End point description:

An AE is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as AEs. AEs were reported based on the NCI-CTCAE, v4.0. As pre-specified in the protocol data reported is combined for Arms G and H. Values have been rounded off to the nearest whole number. Safety population consisted of all ITT participants from Arm G and H (Phase II NF Cohort) who received at least one dose of study medication.

End point type	Primary

End point timeframe:

From Month 37 to Month 84 (up to approximately 47 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for NF cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for arm G and H, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: percentage of participants				
number (not applicable)	99.1			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1a (Phase Ib): Percentage of Participants with Treatment Emergent Anti-Drug Antibodies (ADAs) to Polatuzumab Vedotin

End point title	Cohort 1a (Phase Ib): Percentage of Participants with Treatment Emergent Anti-Drug Antibodies (ADAs) to Polatuzumab Vedotin[5][6]

End point description:

The number of participants with positive results for ADA against pola at Baseline & at any of the post-baseline assessment time-points were reported. Participants positive at any post-baseline timepoints were post-baseline evaluable participants determined to have Treatment-induced ADAs or Treatment-enhanced ADA during the study period. Treatment-induced ADA=negative or missing baseline ADA result(s) & at least one positive post-baseline ADA result. Treatment-enhanced ADA=a participant with positive ADA result at baseline who has one or more post-baseline titer results that are at least 0.60 titer unit (t.u.) greater than the baseline titer result. Treatment emergent ADA is the sum of treatment-induced ADAs & treatment enhanced ADAs. Values have been rounded off to the nearest whole number. Safety population consisted of all ITT participants from Cohort 1a (Phase Ib) who received at least one dose of study medication.

End point type	Primary

End point timeframe:

Baseline up to approximately Month 24

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for Phase Ia cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.
[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: This endpoint was only for Cohort 1a, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: percentage of participants				
number (not applicable)				
Baseline Prevalence of ADAs	50.0	33.3		
Post-Baseline Incidence of ADAs	0	33.3		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1b (Phase Ib): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin and Obinutuzumab

End point title	Cohort 1b (Phase Ib): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin and Obinutuzumab[7][8]

End point description:

Number of participants with positive results for ADA against pola at Baseline & at any of the post-baseline assessment time-points were reported. Participants positive at any post-baseline timepoints=post-baseline evaluable participants determined to have Treatment-induced

ADAs/Treatment-enhanced ADA during the study period. Treatment-induced ADA=negative or missing baseline ADA result(s) & at least one positive post-baseline ADA result. Treatment-enhanced ADA=a participant with positive ADA result at baseline who has one or more post-baseline titer results that are at least 0.60 t.u. > baseline titer result. Treatment emergent ADA is the sum of treatment-induced ADAs & treatment enhanced ADAs. Values have been rounded off to the nearest whole number. Safety population=all ITT participants from Cohort 1b (Phase Ib) who received at least one dose of study medication. 'Number Analysed'=number of participants with data available for analysis at the specified time point.

End point type	Primary

End point timeframe:

Baseline up to approximately Month 24

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for Phase Ia cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint..
[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for Cohort 1b, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: percentage of participants				
Baseline Prevalence of ADAs: Pola (n=6,6)	0	0		
Post-Baseline ADAs: Pola (n=6,6)	0	0		
Baseline Prevalence: ADAs to Obinutuzumab(n=6,5)	0	0		
Post-Baseline ADA: Obinutuzumab (n=6,6)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Arms G+H: (Phase II NF Cohorts): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin (Lyophilized)

End point title	Arms G+H: (Phase II NF Cohorts): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin (Lyophilized)[9]

End point description:

Participants with positive results for ADA against pola at Baseline & any post-baseline assessment time-points were reported. Participants positive at any post-baseline time points were post-baseline evaluable participants determined to have Treatment-induced ADAs/Treatment-enhanced ADAs during the study period. Treatment-induced ADA=negative or missing baseline ADA result(s)&at least one positive post-baseline ADA result. Treatment-enhanced ADA=a participant with positive ADA result at baseline who has one or more post-baseline titer results that are at least 0.60 t.u.>baseline titer result. Treatment emergent ADA=treatment-induced ADAs+treatment enhanced ADAs. Values are rounded off to nearest whole number.Safety population=ITT participants in Arms G&H who received at least one dose of study medication. 'Overall Number Analysed'=participants with data available for analysis. 'Number Analysed'=number of participants with data available for analysis at a specified timepoint.

End point type	Primary

End point timeframe:

From Month 37 to Month 84 (up to approximately 47 months)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for arms G and H, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL	Arm H (Phase II NF Cohort): Pola+BR in DLBCL		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	62		
Units: percentage of participants				
number (not applicable)				
Baseline Prevalence of ADAs: Pola (n=41,62)	0.0	1.6		
Post-Baseline ADAs: Pola (n=39,60)	2.6	5.0		

Statistical analyses

No statistical analyses for this end point

Primary: Phase II Randomised and NF Cohorts: Percentage of Participants with Complete Response (CR) at Primary Response Assessment (PRA) Based on Positron Emission Tomography (PET)-Computed Tomography (CT) Scan as Determined by Independent Review Committee (IRC)

End point title	Phase II Randomised and NF Cohorts: Percentage of Participants with Complete Response (CR) at Primary Response Assessment (PRA) Based on Positron Emission Tomography (PET)-Computed Tomography (CT) Scan as Determined by Independent Review Committee (IRC)[10]

End point description:

CR was assessed by IRC at PRA according to Modified Lugano Response Criteria (MLRC). Per MLRC, CR based on PET-CT was defined as complete metabolic response (MR) in lymph nodes and extralymphatic sites (ELS) with a score of 1, 2, or 3 with or without residual mass, on 5-point scale (5PS) where 1=no uptake above background; 2=uptake≤mediastinum; 3=uptake>mediastinum but≤liver; 4=uptake moderately>liver; 5=uptake markedly higher than liver and/or new lesions no evidence of fluorodeoxyglucose (FDG)-avid disease in bone marrow. Bone marrow is normal by morphology; if indeterminate, immunohistochemistry (IHC) negative. As pre-specified in the protocol data reported is combined for Arms G and H. The analysis was done 6-8 weeks after Cycle 6, Day 1or after final dose of study treatment. Values have been rounded off to the nearest whole number. ITT population=all randomised participants in Phase II Randomised and NF cohorts irrespective of whether or not they received the study treatment.

End point type	Primary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for NF cohorts, hence no descriptive statistics were planned for other cohorts.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	69.2 (52.43 to 82.98)	63.4 (46.94 to 77.88)	42.5 (27.04 to 59.11)	17.5 (7.34 to 32.78)

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: percentage of participants				
number (confidence interval 95%)	39.6 (30.25 to 49.59)			

Statistical analyses

Statistical analysis title	Arm A vs Arm B
Comparison groups	Arm A (Phase II Randomisation): Pola+BR in FL v Arm B (Phase II Randomisation): BR in FL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5353
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	5.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.53
upper limit	25.38

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0128
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates (4.89
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.89
upper limit	42.63

Primary: Arm H (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on PET-CT as Determined by the IRC

End point title	Arm H (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on PET-CT as Determined by the IRC[11]

End point description:

CR was assessed by IRC at PRA according to MLRC. Per MLRC, CR based on PET-CT was defined as complete MR in lymph nodes and ELS with a score of 1, 2, or 3 with or without residual mass, on 5PS where 1=no uptake above background; 2=uptake ≤ mediastinum; 3=uptake > mediastinum but ≤ liver; 4=uptake moderately > liver; 5=uptake markedly higher than liver and/or new lesions no evidence of FDG-avid disease in bone marrow. Bone marrow is normal by morphology; if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts) or after final dose of study treatment. Values have been rounded off to the nearest whole number. ITT population included all randomised participants in Arm H (Phase II NF Cohort) irrespective of whether or not they received the study treatment.

End point type	Primary

End point timeframe:

6-8 weeks after Cycle 6, Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to approximately 23 weeks)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for arm H, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: percentage of participants				
number (confidence interval 95%)	42.2 (29.94 to 55.18)			

Statistical analyses

No statistical analyses for this end point

Primary: Arm G (Phase II NF Cohort): Area Under Concentration-Time Curve (AUC) of Polatuzumab Vedotin (Lyophilized)

End point title	Arm G (Phase II NF Cohort): Area Under Concentration-Time Curve (AUC) of Polatuzumab Vedotin (Lyophilized)[12]

End point description:

Pharmacokinetic (PK) of three pola-related analytes: antibody conjugated monomethyl auristatin E (acMMAE), total antibody, and unconjugated MMAE were measured. The unit of measure for AUC is nanograms*day per millilitres. PK population included all ITT participants in Arm G (Phase II NF Cohort) who received at least one study treatment and who provided suitable PK samples. 'Number Analysed' is the number of participants with data available for analysis at the specified time point. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint.

End point type	Primary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4, (each cycle is 21 days DLBCL cohorts) up to approximately 9 weeks

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for arm G, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	32			
Units: ng*day/mL				
geometric mean (geometric coefficient of variation)				
acMMAE (n=32)	2880 (± 0.15)			
Total Antibody (Ab) (n=0)	999999 (± 999999)			
MMAE (n=32)	21.6 (± 45)			

Statistical analyses

No statistical analyses for this end point

Primary: Arm G (Phase II NF Cohort): Maximum Concentration (Cmax) of Polatuzumab Vedotin (Lyophilized)

End point title	Arm G (Phase II NF Cohort): Maximum Concentration (Cmax) of Polatuzumab Vedotin (Lyophilized)[13]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. PK evaluable population included all the ITT participants in Arm G (Phase II NF Cohort) who received at least one study treatment and who provided suitable PK samples. Here, 999999= participants were not analysed for this PK endpoint at the given timepoint. 'Number Analysed' is the number of participants with data available for analysis at the specified time point.

End point type	Primary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4,(cycle length is 21 days for DLBCL cohorts) up to approximately 9 weeks

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for arm G, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	32			
Units: nanograms per millilitres (ng/mL)				
geometric mean (geometric coefficient of variation)				
acMMAE (n=32)	724 (± 10)			
Total Ab (n=0)	999999 (± 999999)			
MMAE (n=32)	2.01 (± 38)			

Statistical analyses

No statistical analyses for this end point

Primary: Arm G (Phase II NF Cohort): Steady-State Volume of Distribution (Vss) of Polatuzumab Vedotin (Lyophilized)

End point title	Arm G (Phase II NF Cohort): Steady-State Volume of Distribution (Vss) of Polatuzumab Vedotin (Lyophilized)[14]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. As pre-specified in the protocol the analysis of this endpoint was based on sponsor's discretion however, sponsor opted to not collect data for this endpoint.

End point type	Primary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4, Day (cycle length is 21 days for DLBCL cohorts) up to approximately 9 weeks

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for arm G, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	0[15]			
Units: millilitres per kilogram (mL/kg)				
geometric mean (geometric coefficient of variation)	()			

Notes:

[15] - Data was not collected for this endpoint per the sponsor's discretion.

Statistical analyses

No statistical analyses for this end point

Primary: Arm G (Phase II NF Cohort): Systemic Clearance (CL) of Polatuzumab Vedotin (Lyophilized)

End point title	Arm G (Phase II NF Cohort): Systemic Clearance (CL) of Polatuzumab Vedotin (Lyophilized)[16]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Unit of measure for CL is millilitres per day per kilograms (mL/day/kg). As pre-specified in the protocol the analysis of this endpoint was based on sponsor's discretion however, sponsor opted to not collect data for this endpoint.

End point type	Primary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4, (cycle length is 21 days for DLBCL cohorts) up to approximately 9 weeks

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was only for arm G, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	0[17]			
Units: mL/day/kg				
geometric mean (geometric coefficient of variation)	()			

Notes:

[17] - Data was not collected for this endpoint per the sponsor's discretion.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Percentage of Participants with AEs

End point title	Phase II: Percentage of Participants with AEs[18]

End point description:

An AE is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as AEs. AEs were reported based on the NCI-CTCAE, v4.0. As pre-specified in the protocol data reported is combined for Arms G and H. Values have been rounded off to the nearest whole number. Safety population consisted of all ITT participants from Phase II who received at least one dose of study medication.

End point type	Secondary

End point timeframe:

From the study start up to the end of the study (up to approximately 84 months)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	39	39
Units: percentage of participants				
number (not applicable)	100	100	100	97.4

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	20	106	
Units: percentage of participants				
number (not applicable)	100	100	99.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Arms A and C (Phase II): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin

End point title	Arms A and C (Phase II): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin[19]

End point description:

Participants with positive results for ADA against pola at Baseline & any of the post-baseline assessment time-points were reported. Participants positive at any post-baseline time points=post-baseline evaluable participants determined to have Treatment-induced ADAs/Treatment-enhanced ADA during the study period. Treatment-induced ADA=negative or missing baseline ADA result(s)&at least one positive post-baseline ADA result. Treatment-enhanced ADA=a participant with positive ADA result at baseline who has one or more post-baseline titer results that are at least 0.60 t.u.>baseline titer result. Treatment emergent ADA=treatment-induced ADAs+treatment enhanced ADAs.Values are rounded off to the nearest whole number. Safety population=ITT participants in Arms A&C who received at least one dose of study medication. 'Overall Number Analysed'=participants with data available for analysis. 'Number Analysed'=number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Baseline to approximately Month 24

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 only for arms A and C, hence no descriptive statistics were planned for

other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	36		
Units: percentage of participants				
number (not applicable)				
Baseline Prevalence of ADAs (n=37,36)	0	0		
Post-Baseline ADAs (n=38,35)	7.9	2.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Arms E and F (Phase II): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin and Obinutuzumab

End point title	Arms E and F (Phase II): Percentage of Participants with Treatment Emergent ADAs to Polatuzumab Vedotin and Obinutuzumab[20]

End point description:

The number of participants with positive results for ADA against pola and obinutuzumab at Baseline and at any post-baseline assessment time-points were reported. Participants positive at any post-baseline time points were post-baseline evaluable participants with “Treatment-induced ADAs” or “Treatment-enhanced ADA” during study period. Treatment-induced ADA=negative or missing baseline ADA result(s) and at least one positive post-baseline ADA result. Treatment-enhanced ADA=participant with positive ADA result at baseline who has one or more post-baseline titer results that are at least 0.60 t.u. greater than the baseline titer result. Treatment emergent ADA=of treatment-induced ADAs+treatment enhanced ADAs. Values have been rounded off to the nearest whole number. Safety population=ITT participants from Arm E and F (Phase II)who received at least one dose of study medication. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Baseline to approximately Month 24

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for arms E and F, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: percentage of participants				
number (not applicable)				
Baseline Prevalence of ADAs: Pola (n=19,18)	0	0		

Post-Baseline ADAs: Pola (n=19,18)	5.3	5.6		
Baseline Prevalence of ADAs: Obinutuzumab(n=20,20)	0	0		
Post-Baseline ADAs: Obinutuzumab (n=19,18)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Percentage of Participants with CR at PRA Based on PET-CT as Determined by the Investigator

End point title	Phase II: Percentage of Participants with CR at PRA Based on PET-CT as Determined by the Investigator[21]

End point description:

CR was assessed by investigator at PRA according to MLRC. Per MLRC, CR based on PET-CT was defined as complete MR in lymph nodes and ELS with a score of 1, 2, or 3 with or without residual mass, on 5PS where 1=no uptake above background; 2=uptake ≤ mediastinum; 3=uptake > mediastinum but ≤ liver; 4=uptake moderately > liver; 5=uptake markedly higher than liver and/or new lesions no evidence of FDG-avid disease in bone marrow. Bone marrow=normal by morphology; if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts and 28 days for FL cohorts) or after final dose of study treatment. As pre-specified in the protocol data reported is combined for Arms G and H. Values have been rounded off to the nearest whole number. ITT population included all randomised participants in Phase II irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	64.1 (47.18 to 78.80)	63.4 (46.94 to 77.88)	42.5 (27.04 to 59.11)	15.0 (5.71 to 29.84)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	21	106	

Units: percentage of participants				
number (confidence interval 95%)	65.0 (40.78 to 84.61)	33.3 (14.59 to 56.97)	36.8 (27.63 to 46.71)	

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0061
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	27.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.66
upper limit	44.74

Statistical analysis title	Arm A vs Arm B
Comparison groups	Arm A (Phase II Randomisation): Pola+BR in FL v Arm B (Phase II Randomisation): BR in FL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8817
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.68
upper limit	20.86

Secondary: Phase II Expansion Cohorts and Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on PET-CT as Determined by the IRC

End point title	Phase II Expansion Cohorts and Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on PET-CT as Determined by the IRC[22]

End point description:

CR was assessed by IRC at PRA according to MLRC. Per MLRC, CR based on PET-CT was defined as

complete MR in lymph nodes and ELS with a score of 1, 2, or 3 with or without residual mass, on 5PS where 1=no uptake above background; 2=uptake ≤ mediastinum; 3=uptake > mediastinum but ≤ liver; 4=uptake moderately > liver; 5=uptake markedly higher than liver and/or new lesions no evidence of FDG-avid disease in bone marrow. Bone marrow is normal by morphology; if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts and 28 days for FL cohorts) or after final dose of study treatment. Values have been rounded off to the nearest whole number. ITT population included all randomised participants in Phase II Expansion Cohorts and Arm G (Phase II NF Cohort) irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for arm G, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	20	21	42	
Units: percentage of participants				
number (confidence interval 95%)	65.0 (40.78 to 84.61)	33.3 (14.59 to 56.97)	35.7 (21.55 to 51.97)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Percentage of Participants with Objective Response (OR) at PRA Based on PET-CT as Determined by Investigator

End point title	Phase II: Percentage of Participants with Objective Response (OR) at PRA Based on PET-CT as Determined by Investigator[23]

End point description:

OR at PRA=percentage of participants with CR/PR at PRA, assessed by investigator per MLRC. Per MLRC, CR per PET-CT=complete MR in lymph nodes(LN) and ELS with a score of 1, 2, or3 with/without residual mass on 5PS, i.e. 1=no uptake above background;2=uptake ≤ mediastinum;3=uptake mediastinum but ≤ liver;4=uptake moderately > liver;5=uptake markedly higher than liver and/or new lesions;no evidence of FDG-avid disease in bone marrow, normal by morphology; if indeterminate, IHC negative. PR perPET-CT=partial MR in LN and ELS with a score of 4/5 with reduced uptake compared with baseline (B) and residual mass(es) of any size at interim, residual uptake higher than uptake in normal bone marrow but reduced compared with B (diffuse uptake compatible with reactive changes from chemotherapy allowed). ITT population=all randomised participants in Phase II irrespective of whether/not they received the study treatment. As pre-specified in the protocol data reported is combined for Arms G and H.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length 21 for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	79.5 (63.54 to 90.70)	80.5 (63.13 to 91.18)	47.5 (31.51 to 63.87)	17.5 (7.34 to 32.78)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	21	106	
Units: percentage of participants				
number (confidence interval 95%)	85.0 (62.11 to 96.79)	33.3 (14.59 to 56.97)	42.5 (32.91 to 52.43)	

Statistical analyses

Statistical analysis title	Arm A vs Arm B
Comparison groups	Arm A (Phase II Randomisation): Pola+BR in FL v Arm B (Phase II Randomisation): BR in FL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9523
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.66
upper limit	16.46

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0036
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	30
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.48
upper limit	47.37

Secondary: Phase II: Percentage of Participants with OR at PRA Based on PET-CT as Determined by IRC

End point title	Phase II: Percentage of Participants with OR at PRA Based on PET-CT as Determined by IRC[24]

End point description:

OR at PRA=percentage of participants with CR/PR at PRA, assessed by investigator per MLRC. Per MLRC, CR per PET-C=complete MR in LN and ELS with a score of 1, 2, or 3 with/without residual mass on 5PS, i.e.1=no uptake above background;2=uptake ≤ mediastinum;3=uptake mediastinum but ≤ liver;4=uptake moderately > liver;5=uptake markedly higher than liver and/or new lesions;no evidence of FDG-avid disease in bone marrow, normal by morphology; if indeterminate, IHC negative. PR perPET-CT=partial MR in LN and ELS with a score of 4/5 with reduced uptake compared with baseline (B) and residual mass(es) of any size at interim, residual uptake higher than uptake in normal bone marrow but reduced compared with B (diffuse uptake compatible with reactive changes from chemotherapy allowed). ITT population=all randomised participants in Phase II irrespective of whether/not they received the study treatment. As pre-specified in the protocol data reported is combined for Arms G and H.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	76.9 (60.67 to 88.87)	73.2 (57.06 to 85.78)	42.5 (27.04 to 59.11)	17.5 (7.34 to 32.78)

End point values	Arm E (Phase II Expansion):	Arm F (Phase II Expansion):	Arm G+H (Phase II NF	

	Pola+BG in FL	Pola+BG in DLBCL	Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	21	106	
Units: percentage of participants				
number (confidence interval 95%)	85.0 (62.11 to 96.79)	38.1 (18.11 to 61.56)	43.4 (33.80 to 53.37)	

Statistical analyses

Statistical analysis title	Arm A vs Arm B
Comparison groups	Arm A (Phase II Randomisation): Pola+BR in FL v Arm B (Phase II Randomisation): BR in FL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6574
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	3.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.14
upper limit	22.11

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0128
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.89
upper limit	42.63

Secondary: Phase II: Percentage of Participants with CR at PRA Based on CT only as Determined by Investigator

End point title	Phase II: Percentage of Participants with CR at PRA Based on

	CT only as Determined by Investigator[25]

End point description:

CR was determined by investigator at PRA per MLRC. Per MLRC, CR based on CT was defined as complete radiologic response in lymph nodes and ELS with target nodes/nodal masses regressing to ≤ 1.5 centimetres (cm) in longest transverse diameter (LDi) and no ELS of disease organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts and 28 days for FL cohorts). As pre-specified in the protocol data reported is combined for Arms G and H. Values have been rounded off to the nearest whole number. ITT population included all randomised participants in Phase II irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

Notes:

[25] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm B (Phase II Randomisation) : BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL	Arm D (Phase II Randomisation) : BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	46.2 (30.09 to 62.82)	19.5 (8.82 to 34.87)	20.0 (9.05 to 35.65)	5.0 (0.61 to 16.92)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	21	106	
Units: percentage of participants				
number (confidence interval 95%)	20.0 (5.73 to 43.66)	14.3 (3.05 to 36.34)	14.2 (8.14 to 22.26)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Percentage of Participants with CR at PRA Based on CT Only as Determined by IRC

End point title	Phase II: Percentage of Participants with CR at PRA Based on CT Only as Determined by IRC[26]

End point description:

CR was determined by IRC at PRA according to the MLRC. Per MLRC, CR based on CT was defined as complete radiologic response in lymph nodes (LN) and ELS with target nodes/nodal masses regressing

to ≤ 1.5 cm in LDi and no ELS of disease organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts and 28 days for FL cohorts). ITT population included all randomised participants in Phase II irrespective of whether or not they received the study treatment. As pre-specified in the protocol data reported is combined for Arms G and H. Values have been rounded off to the nearest whole number.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

Notes:

[26] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm B (Phase II Randomisation) : BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL	Arm D (Phase II Randomisation) : BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	41.0 (25.57 to 57.90)	36.6 (22.12 to 53.06)	22.5 (10.84 to 38.45)	2.5 (0.06 to 13.16)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	20	106	
Units: percentage of participants				
number (confidence interval 95%)	50.0 (27.20 to 72.80)	23.8 (8.22 to 47.17)	17.9 (11.5 to 26.57)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Percentage of Participants with OR at PRA Based on CT only as Determined by Investigator

End point title	Phase II: Percentage of Participants with OR at PRA Based on CT only as Determined by Investigator[27]

End point description:

OR at PRA=percentage of participants with CR/PR at PRA, assessed by investigator per MLRC. Per MLRC, CR based on CT=complete radiologic response in LN & ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi and no ELS of disease, organ enlargement regressing to normal; no new lesions; bone marrow normal by morphology, if indeterminate, IHC negative. PR per CT only=partial remission in LN and ELS with ≥50% decrease in sum of the products of greatest diameters (SPD) of up to 6 target measurable LN and extranodal sites, absent/normal/regressed but with no increase in non-measured

lesions, spleen regressing by ≥50% in length beyond normal it, no new sites of lesions. As pre-specified in protocol data is reported combined for Arms G & H. ITT population=all randomised participants in Phase II irrespective of whether or not they received the study treatment. Values have been rounded off to the nearest whole number.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	79.5 (63.54 to 90.70)	75.6 (59.70 to 87.64)	45.0 (29.26 to 61.51)	15.0 (5.71 to 29.84)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	21	106	
Units: percentage of participants				
number (confidence interval 95%)	80.0 (56.34 to 94.27)	33.3 (14.59 to 56.97)	42.5 (32.91 to 52.43)	

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0032
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	30

Confidence interval	
level	95 %
sides	2-sided
lower limit	9.94
upper limit	47.12

Statistical analysis title	Arm A vs Arm B
Comparison groups	Arm A (Phase II Randomisation): Pola+BR in FL v Arm B (Phase II Randomisation): BR in FL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6225
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	3.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.49
upper limit	21.72

Secondary: Phase II: Percentage of Participants with OR at PRA Based on CT only as Determined by IRC

End point title	Phase II: Percentage of Participants with OR at PRA Based on CT only as Determined by IRC[28]

End point description:

OR at PRA=percentage of participants with CR or PR at PRA, assessed by IRC per MLRC. Per MLRC, CR based on CT=complete radiologic response in LN & ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi and no ELS of disease, organ enlargement regressing to normal; no new lesions; bone marrow normal by morphology, if indeterminate, IHC negative. PR per CT only=partial remission in LN and ELS with ≥ 50% decrease in SPD of up to 6 target measurable LN and extranodal sites, absent/normal/regressed but with no increase in non-measured lesions, spleen regressing by ≥50% in length beyond normal it, no new sites of lesions. Analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle=21 days=DLBCL cohorts & 28 days=FL cohorts). As pre-specified in the protocol data is reported combined for Arms G & H. ITT population=all randomised participants in Phase II irrespective of whether or not they received the study treatment. Values have been rounded off to the nearest whole number.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts) or last dose of study drug (up to approximately 28 weeks)

Notes:

[28] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	74.4 (57.87 to 86.96)	80.5 (65.13 to 91.18)	40.0 (24.86 to 56.67)	15.0 (5.71 to 29.84)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	21	106	
Units: percentage of participants				
number (confidence interval 95%)	80.0 (56.34 to 94.27)	38.1 (18.11 to 61.56)	41.5 (32.02 to 51.49)	

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0096
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.39
upper limit	42.33

Statistical analysis title	Arm A vs Arm B
Comparison groups	Arm A (Phase II Randomisation): Pola+BR in FL v Arm B (Phase II Randomisation): BR in FL

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4835
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	-6.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.14
upper limit	12.12

Secondary: Phase II: Percentage of Participants with Best Objective Response (BOR) Based on PET-CT or CT Only as Determined by the Investigator

End point title	Phase II: Percentage of Participants with Best Objective Response (BOR) Based on PET-CT or CT Only as Determined by the Investigator[29]

End point description:

BOR=CR/PR per PET-CT/CT per MLRC.CR per PET-CT=completeMR in LN & ELS, score=1, 2,3 with/without a residual mass on 5-PS;1=no uptake(UT) above background;2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UTmarkedly higher than liver &/or new lesions;no evidence of FDG-avid disease, bone marrow morphology normal;if indeterminate,IHC negative.PR per PET-CT=partial MR in LN & ELS, score=4 or 5, reduced UT than baseline (BL) & residual mass of any size;residual UT>UT in normal marrow but reduced than BL.CR per CT=complete radiologic response with target nodes/nodal masses regressed to ≤1.5cm in LDi &no ELS of disease, absences of non-measured lesion;organ enlargement regressed to normal;no new lesions;bone marrow=normal;if indeterminate,IHC negative.PR per CT=≥50% decrease in SPD of up to6 target nodes& extranodal sites;non-measured lesions=absent/normal/regressed/no increase;spleen=regressed by ≥50% in length beyond normal, no new lesions. ITT population.

End point type	Secondary

End point timeframe:

Up to every 6 months until disease progression, withdrawal or study completion (up to approximately 84 months)

Notes:

[29] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm B (Phase II Randomisation) : BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL	Arm D (Phase II Randomisation) : BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	40
Units: percentage of participants				
number (confidence interval 95%)	89.7 (75.78 to 97.13)	90.2 (76.87 to 97.28)	70.0 (53.47 to 83.44)	32.5 (18.57 to 49.13)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	21	106	
Units: percentage of participants				
number (confidence interval 95%)	90.0 (68.30 to 98.77)	52.4 (29.78 to 74.29)	62.3 (52.33 to 71.50)	

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	37.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.64
upper limit	54.71

Statistical analysis title	Arm A vs Arm B
Comparison groups	Arm A (Phase II Randomisation): Pola+BR in FL v Arm B (Phase II Randomisation): BR in FL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.939
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.07
upper limit	13.71

Secondary: DLBCL Cohorts: Percentage of Participants with BOR based PET-CT or CT

Only as Determined by IRC

End point title	DLBCL Cohorts: Percentage of Participants with BOR based PET-CT or CT Only as Determined by IRC[30]

End point description:

BOR=CR/PR per PET-CT/CT per MLRC. CR per PET-CT=complete MR in LN & ELS, score=1, 2,3 with/without residual mass on 5-PS;1=no UT above background;2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UT markedly higher than liver &/or new lesions; no evidence of FDG-avid disease, bone marrow morphology normal; if indeterminate, IHC negative.PR per PET-CT=partial MR in LN & ELS, score=4/5, reduced UT than BL &residual mass of any size; residual UT>UT in normal marrow but reduced thanBL.CR per CT=complete radiologic response with target nodes/nodal masses regressed to≤1.5cm in LDi & no ELS of disease, absences of non-measured lesion; organ enlargement regressed to normal; no new lesions; bone marrow=normal; if indeterminate, IHC negative.PR per CT=≥50% decrease in SPD of up to 6 target nodes& extranodal sites;non-measured lesions=absent/normal/regressed/no increase;spleen=regressed by≥50% in length beyond normal, no new lesions. ITT population.

End point type	Secondary

End point timeframe:

Up to every 6 months until disease progression, withdrawal or study completion (up to approximately 84 months)

Notes:

[30] - 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 only for DLBCL cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	21	106
Units: percentage of participants				
number (confidence interval 95%)	62.5 (45.80 to 77.27)	25.0 (12.69 to 41.20)	42.9 (21.82 to 65.98)	57.5 (47.57 to 67.09)

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0005
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	37.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.82
upper limit	54.62

Secondary: DLBCL Cohorts: Duration of Response (DOR) Based on PET-CT or CT Only as Determined by the Investigator

End point title	DLBCL Cohorts: Duration of Response (DOR) Based on PET-CT or CT Only as Determined by the Investigator[31]

End point description:

DOR=first occurrence of CR/PR to disease progression/relapse/death per PET-CT/CT, per investigator per MLRC.CR per PET-CT=score 1/2/3 with/without a residual mass on 5-PS for LN and ELS;1=no UT> background; 2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UT>than liver &/or new lesions;bone marrow morphology=no evidence of FDG-avid disease, normal;if indeterminate IHC negative.PR per PET-CT=score of 4/5 with reduced UT compared to BL&residual mass of any size at interim for LN & ELS;residual UT>UT in normal bone marrow but<than BL.CR per CT=target nodes/nodal masses regressed to ≤1.5cm in LDi no ELS of disease for LN & ELS, no non-measured lesion, organ enlargement regressed to normal; bone marrow=normal morphology; if indeterminate, IHC negative. PR per CT= ≥50% decrease SPD of 6 target measurable LN&extranodal sites, absent/normal/regressed but no<in non-measured lesions, spleen ≥50% in length beyond normal involvement, no new sites of lesions. ITT population.

End point type	Secondary

End point timeframe:

From the date of the first occurrence of a documented CR or PR to the date of disease progression, relapse, or death from any cause whichever occur first (up to approximately 84 months)

Notes:

[31] - 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 only for DLBCL cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	28	13	11	66
Units: months				
median (confidence interval 95%)	12.665 (5.782 to 27.926)	4.074 (2.563 to 12.682)	16.099 (2.825 to 27.860)	11.335 (6.242 to 16.197)

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0245
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.42

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	0.91

Secondary: DLBCL Cohorts: DOR Based on PET-CT or CT Only as Determined by the IRC

End point title	DLBCL Cohorts: DOR Based on PET-CT or CT Only as Determined by the IRC[32]

End point description:

DOR=first occurrence of CR/PR to disease progression/relapse/death per PET-CT/CT, per investigator per MLRC.CR per PET-CT=score 1/2/3 with/without a residual mass on 5-PS for LN and ELS;1=no UT> background; 2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UT>than liver &/or new lesions;bone marrow morphology=no evidence of FDG-avid disease, normal;if indeterminate IHC negative.PR per PET-CT=score of 4/5 with reduced UT compared to BL&residual mass of any size at interim for LN & ELS;residual UT>UT in normal bone marrow but<than BL.CR per CT=target nodes/nodal masses regressed to ≤1.5cm in LDi no ELS of disease for LN & ELS, no non-measured lesion, organ enlargement regressed to normal; bone marrow=normal morphology; if indeterminate, IHC negative. PR per CT= ≥50% decrease SPD of 6 target measurable LN&extranodal sites, absent/normal/regressed but no<in non-measured lesions, spleen ≥50% in length beyond normal involvement, no new sites of lesions. ITT population.

End point type	Secondary

End point timeframe:

From the date of the first occurrence of a documented CR or PR to the date of disease progression, relapse, or death from any cause whichever occur first (up to approximately 84 months)

Notes:

[32] - 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 only for DLBCL cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	25	10	9	61
Units: months				
median (confidence interval 95%)	10.908 (5.684 to 40.674)	10.645 (3.975 to 19.647)	25.758 (9.692 to 46.752)	13.437 (8.641 to 20.041)

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL

Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2451
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	1.43

Secondary: DLBCL Cohorts: Progression Free Survival (PFS) Based on PET-CT or CT Only as Determined by the Investigator

End point title	DLBCL Cohorts: Progression Free Survival (PFS) Based on PET-CT or CT Only as Determined by the Investigator[33]

End point description:

PFS was defined as the time randomisation or from first study treatment (for obinuzumab arms) to the first occurrence of disease progression, relapse or death, from any cause based on PET-CT or CT only, as determined by the investigators assessment. As pre-specified in the protocol data is reported combined for Arms G and H. ITT population included all randomised participants in DLBCL cohorts irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

From the date of randomization or first treatment to the first occurrence of progression or relapse, or death from any cause (up to approximately 84 months)

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 only for DLBCL cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	21	106
Units: months				
median (confidence interval 95%)	7.491 (4.928 to 16.953)	2.037 (1.544 to 3.713)	5.125 (2.103 to 18.234)	5.881 (4.764 to 7.524)

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	0.56

Secondary: DLBCL Cohorts: PFS Based on PET-CT or CT Only as Determined by the IRC

End point title	DLBCL Cohorts: PFS Based on PET-CT or CT Only as Determined by the IRC[34]

End point description:

PFS was defined as the time randomisation or from first study treatment (for obinuzumab arms) to the first occurrence of disease progression, relapse or death, from any cause based on PET-CT or CT only, as determined by the IRC assessment. As pre-specified in the protocol data is reported combined for Arms G and H. ITT population included all randomised participants in DLBCL cohorts irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

From the date of randomisation or first treatment to the first occurrence of progression or relapse, or death from any cause (up to approximately 84 months)

Notes:

[34] - 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 only for DLBCL cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	21	106
Units: months				
median (confidence interval 95%)	9.248 (6.045 to 13.930)	3.713 (2.070 to 4.534)	5.848 (2.103 to 11.893)	6.965 (5.092 to 9.823)

Statistical analyses

Statistical analysis title	Arm C vs Arm D
Comparison groups	Arm C (Phase II Randomisation): Pola+BR in DLBCL v Arm D (Phase II Randomisation): BR in DLBCL

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0003
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	0.66

Secondary: Phase II NF Cohort: Percentage of Participants with CR at PRA Based on PET-CT as Determined by the Investigator

End point title	Phase II NF Cohort: Percentage of Participants with CR at PRA Based on PET-CT as Determined by the Investigator[35]

End point description:

CR was assessed by Investigator at PRA according to MLRC. Per MLRC, CR based on PET-CT was defined as complete MR in lymph nodes and ELS with a score of 1, 2, or 3 with or without residual mass, on 5PS where 1=no uptake above background; 2=uptake ≤ mediastinum; 3=uptake > mediastinum but ≤ liver; 4=uptake moderately > liver; 5=uptake markedly higher than liver and/or new lesions no evidence of FDG-avid disease in bone marrow. Bone marrow is normal by morphology; if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts) or after final dose of study treatment. Values have been rounded off to the nearest whole number. As pre-specified in the protocol data is reported combined for Arms G and H. ITT population included all randomised participants in Phase II NF cohort irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length 21) or last dose of study drug (up to approximately 23 weeks)

Notes:

[35] - 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 only for Phase II NF cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: percentage of participants				
number (confidence interval 95%)	36.8 (27.63 to 46.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohort: Percentage of Participants with OR at PRA Based on PET-CT as Determined by Investigator

End point title	Phase II NF Cohort: Percentage of Participants with OR at PRA Based on PET-CT as Determined by Investigator[36]

End point description:

OR at PRA=percentage of participants with CR/PR at PRA, assessed by investigator per MLRC. Per MLRC, CR per PET-CT=complete MR in LN & ELS with a score of 1, 2, or 3 with/without residual mass on 5PS, i.e., 1=no uptake above background;2=uptake ≤ mediastinum;3=uptake mediastinum but ≤ liver;4=uptake moderately > liver;5=uptake markedly higher than liver &/or new lesions; no evidence of FDG-avid disease in bone marrow, normal by morphology; if indeterminate, IHC negative. PR per PET-CT=partial MR in LN and ELS with a score of 4/5 with reduced uptake compared with baseline (BL) & residual mass(es) of any size at interim, residual uptake higher than uptake in normal bone marrow but reduced compared with BL (diffuse uptake compatible with reactive changes from chemotherapy allowed). ITT population=all randomised participants in Phase II NF cohort irrespective of whether/not they received the study treatment. As pre-specified in the protocol data reported is combined for Arms G & H.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to approximately 23 weeks)

Notes:

[36] - 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 only for NF cohorts, hence no descriptive statistics were planned for other cohorts.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: percentage of participants				
number (confidence interval 95%)	42.5 (32.91 to 52.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohorts: Percentage of Participants with BOR Based on PET-CT or CT Only as Determined by the IRC

End point title	Phase II NF Cohorts: Percentage of Participants with BOR Based on PET-CT or CT Only as Determined by the IRC[37]

End point description:

BOR=CR/PR per PET-CT/CT per MLRC.CR per PET-CT=complete MR in LN &ELS, score=1, 2,3 with/without a residual mass on 5-PS;1=no UT above background;2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UT markedly higher than liver &/or new lesions; no evidence of FDG-avid disease, bone marrow morphology normal; if indeterminate, IHC negative.PR per PET-CT=partial MR in LN &ELS, score=4 or 5, reduced UT than BL & residual mass of any size; residual UT>UT in normal marrow but reduced than BL. CR per CT=complete radiologic response with target nodes/nodal masses regressed to ≤1.5cm in LDi & no ELS of disease, absences of non-measured lesion; organ enlargement regressed to normal; no new lesions; bone marrow=normal; if

indeterminate, IHC negative.PR per CT=≥50% decrease in SPD of up to6 target nodes& extranodal sites;non-measured lesions=absent/normal/regressed/no increase;spleen=regressed by ≥50% in length beyond normal, no new lesions. ITT population.

End point type	Secondary

End point timeframe:

Up to every 6 months until disease progression, withdrawal or study completion (from Month 37 to Month 84 [up to approximately 47 months])

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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: percentage of participants				
number (confidence interval 95%)	57.5 (47.57 to 67.09)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohorts: Percentage of Participants with BOR Based on PET-CT or CT Only as Determined by the Investigator

End point title	Phase II NF Cohorts: Percentage of Participants with BOR Based on PET-CT or CT Only as Determined by the Investigator[38]

End point description:

BOR=CR/PR per PET-CT/CT per MLRC. CR per PET-CT=complete MR in LN & ELS, score=1, 2,3 with/without residual mass on 5-PS;1=no UT above background;2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UT markedly higher than liver &/or new lesions; no evidence of FDG-avid disease, bone marrow morphology normal; if indeterminate, IHC negative.PR per PET-CT=partial MR in LN & ELS, score=4/5, reduced UT than BL & residual mass of any size; residual UT>UT in normal marrow but reduced thanBL.CR per CT=complete radiologic response with target nodes/nodal masses regressed to≤1.5cm in LDi & no ELS of disease, absences of non-measured lesion; organ enlargement regressed to normal; no new lesions; bone marrow=normal; if indeterminate, IHC negative.PR per CT=≥50% decrease in SPD of up to 6 target nodes& extranodal sites;non-measured lesions=absent/normal/regressed/no increase;spleen=regressed by≥50% in length beyond normal, no new lesions. ITT population.

End point type	Secondary

End point timeframe:

UpUp to every 6 months until disease progression, withdrawal or study completion (from Month 37 to Month 84 [up to approximately 47 months])

Notes:

[38] - 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 only for Phase II NF cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: percentage of participants				
number (confidence interval 95%)	62.3 (52.33 to 71.50)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohort: Percentage of Participants with OR at PRA Based on PET-CT as Determined by IRC

End point title	Phase II NF Cohort: Percentage of Participants with OR at PRA Based on PET-CT as Determined by IRC[39]

End point description:

OR at PRA=percentage of participants with CR/PR at PRA, per the IRC per MLRC. Per MLRC, CR per PET-CT complete MR in LN & ELS with a score of 1, 2, or 3 with or without residual mass on 5PS, where1=no uptake above background;2=uptake ≤ mediastinum;3=uptake mediastinum but≤ liver;4=uptake moderately> liver;5=uptake markedly<than liver &/or new lesions; no new lesions and no evidence of FDG-avid disease in bone marrow, normal morphology; if indeterminate, IHC negative.PR per PET-CT=partial MR in LN and ELS with a score of 4/5 with reduced UT compared with BL & residual mass(es) of any size at interim, residual UT higher than UT in normal bone marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed).As pre-specified in the protocol data is reported combined for Arms G and H. ITT population=all randomised participants in NF cohort irrespective of whether they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to approximately 23 weeks)

Notes:

[39] - 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 only for NF cohorts, hence no descriptive statistics were planned for other cohorts.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: percentage of participants				
number (confidence interval 95%)	43.4 (33.80 to 53.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohort: DOR Based on PET-CT or CT Only as Determined by the Investigator

End point title	Phase II NF Cohort: DOR Based on PET-CT or CT Only as Determined by the Investigator

End point description:

DOR=first occurrence of CR/PR to disease progression/relapse/death per PET-CT/CT, per investigator per MLRC.CR per PET-CT=score 1/2/3 with/without a residual mass on 5-PS for LN and ELS;1=no UT> background; 2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UT>than liver &/or new lesions;bone marrow morphology=no evidence of FDG-avid disease, normal;if indeterminate IHC negative.PR per PET-CT=score of 4/5 with reduced UT compared to BL&residual mass of any size at interim for LN & ELS;residual UT>UT in normal bone marrow but<than BL.CR per CT=target nodes/nodal masses regressed to ≤1.5cm in LDi no ELS of disease for LN & ELS, no non-measured lesion, organ enlargement regressed to normal; bone marrow=normal morphology; if indeterminate, IHC negative. PR per CT= ≥50% decrease SPD of 6 target measurable LN&extranodal sites, absent/normal/regressed but no<in non-measured lesions, spleen ≥50% in length beyond normal involvement, no new sites of lesions. ITT population.

End point type	Secondary

End point timeframe:

From the date of the first occurrence of a documented CR or PR to the date of disease progression, relapse, or death from any cause whichever occur first (from Month 37 to Month 84 [up to approximately 47 months])

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	66			
Units: months				
median (confidence interval 95%)	11.335 (6.242 to 16.197)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohort: DOR Based on PET-CT or CT Only as Determined by the IRC

End point title	Phase II NF Cohort: DOR Based on PET-CT or CT Only as Determined by the IRC

End point description:

DOR=first occurrence of CR/PR to disease progression/relapse/death per PET-CT/CT, per IRC per MLRC.CR per PET-CT=score 1/2/3 with/without a residual mass on 5-PS for LN and ELS;1=no UT> background; 2=UT≤mediastinum;3=UT>mediastinum but ≤liver;4=UT moderately>liver;5=UT>than liver &/or new lesions;bone marrow morphology=no evidence of FDG-avid disease, normal;if indeterminate IHC negative.PR per PET-CT=score of 4/5 with reduced UT compared to BL&residual mass of any size at interim for LN & ELS;residual UT>UT in normal bone marrow but<than BL.CR per CT=target nodes/nodal masses regressed to ≤1.5cm in LDi no ELS of disease for LN & ELS, no non-measured lesion, organ enlargement regressed to normal; bone marrow=normal morphology; if indeterminate, IHC negative. PR per CT= ≥50% decrease SPD of 6 target measurable LN&extranodal sites, absent/normal/regressed but no<in non-measured lesions, spleen ≥50% in length beyond normal

involvement, no new sites of lesions. ITT population.

End point type	Secondary

End point timeframe:

From the date of the first occurrence of a documented CR or PR to the date of disease progression, relapse, or death from any cause whichever occur first (from Month 37 to Month 84 [up to approximately 47 months])

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	61			
Units: months				
median (confidence interval 95%)	13.437 (8.641 to 20.041)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohort: PFS Based on PET-CT or CT Only as Determined by the Investigator

End point title	Phase II NF Cohort: PFS Based on PET-CT or CT Only as Determined by the Investigator[40]

End point description:

PFS was defined as the time from randomisation or from first study treatment (for obinuzumab arms) to the first occurrence of disease progression, relapse or death, from any cause based on PET-CT or CT only, as determined by the investigators assessment. As pre-specified in the protocol data is reported combined for Arms G and H. ITT population included all randomised participants in Phase II NF cohort irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

From the date of randomisation or first treatment to the first occurrence of progression or relapse, or death from any cause (from Month 37 to Month 84 [up to approximately 47 months])

Notes:

[40] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: months				
median (confidence interval 95%)	5.881 (4.764 to 7.524)			

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on PET-CT as Determined by the IRC

End point title	Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on PET-CT as Determined by the IRC

End point description:

CR was assessed by IRC at PRA according to MLRC. Per MLRC, CR based on PET-CT was defined as complete MR in lymph nodes and ELS with a score of 1, 2, or 3 with or without residual mass, on 5PS where 1=no uptake above background; 2=uptake ≤ mediastinum; 3=uptake > mediastinum but ≤ liver; 4=uptake moderately > liver; 5=uptake markedly higher than liver and/or new lesions no evidence of FDG-avid disease in bone marrow. Bone marrow is normal by morphology; if indeterminate, IHC negative. As pre-specified in the protocol Arms G and H have been combined to provide a more precise 95% CI. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts) or after final dose of study treatment. Values have been rounded off to the nearest whole number. ITT population included all randomised participants in Arm G (Phase II NF Cohort) irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to approximately 23 weeks)

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (confidence interval 95%)	35.7 (21.55 to 51.97)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohort: PFS Based on PET-CT or CT Only as Determined by the IRC

End point title	Phase II NF Cohort: PFS Based on PET-CT or CT Only as Determined by the IRC[41]

End point description:

PFS was defined as the time from randomisation or from first study treatment (for obinuzumab arms) to the first occurrence of disease progression, relapse or death, from any cause based on PET-CT or CT

only, as determined by the IRC assessment. As pre-specified in the protocol data is reported combined for Arms G and H. ITT population included all randomised participants in NF cohort irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

From the date of randomisation or first treatment to the first occurrence of progression or relapse, or death from any cause (up to approximately 47 months)

Notes:

[41] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: months				
median (confidence interval 95%)	6.965 (5.092 to 9.823)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohorts: Event-Free Survival (EFS) Based on PET-CT or CT Only, as Determined by the Investigator

End point title	Phase II NF Cohorts: Event-Free Survival (EFS) Based on PET-CT or CT Only, as Determined by the Investigator[42]

End point description:

EFS was defined as time from randomisation to disease progression or relapse, as assessed by the investigator or death from any cause. As pre-specified in the protocol data is reported combined for Arms G and H. ITT population included all randomised participants in Phase II NF cohort irrespective of whether or not they received the study treatment. 'Overall Number Analysed' are the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

From Month 37 to Month 84 (Up to approximately 47 months)

Notes:

[42] - 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 only for Phase II NF cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			

Units: months				
median (confidence interval 95%)	5.092 (4.402 to 6.867)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II NF Cohorts: Overall Survival (OS)

End point title	Phase II NF Cohorts: Overall Survival (OS)[43]

End point description:

OS was defined as the time from the date of randomisation or first treatment (for obinutuzumab arms) to the date of death from any cause. As pre-specified in the protocol data reported is combined for Arms G and H. ITT population included all participants in Phase II NF cohort who were randomised, whether or not the participants received the assigned treatment.

End point type	Secondary

End point timeframe:

From Month 37 to Month 84 (Up to approximately 47 months)

Notes:

[43] - 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 only for Phase II NF cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: months				
median (confidence interval 95%)	12.320 (8.279 to 16.986)			

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on CT only as Determined by IRC

End point title	Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on CT only as Determined by IRC

End point description:

CR was determined by IRC at PRA according to the MLRC. Per MLRC, CR based on CT was defined as complete radiologic response in lymph nodes and ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi and no ELS of disease organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts). Values have been rounded off to the nearest whole number. ITT population included all randomised participants in Arm G (Phase II NF Cohort) irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to approximately 23 weeks)

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (confidence interval 95%)	14.3 (5.43 to 28.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on CT only as Determined by Investigator

End point title	Arm G (Phase II NF Cohort): Percentage of Participants with CR at PRA Based on CT only as Determined by Investigator

End point description:

CR was determined by Investigator at PRA according to the MLRC. Per MLRC, CR based on CT was defined as complete radiologic response in lymph nodes and ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi and no ELS of disease organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, IHC negative. The analysis was done 6-8 weeks after Cycle 6, Day 1 (each cycle is 21 days for DLBCL cohorts). Values have been rounded off to the nearest whole number. ITT population included all randomised participants in Arm G (Phase II NF Cohort) irrespective of whether or not they received the study treatment.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to approximately 23 weeks)

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (confidence interval 95%)	9.5 (2.66 to 22.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of of Polatuzumab Vedotin Analyte: acMMAE

End point title	Plasma Concentration of of Polatuzumab Vedotin Analyte: acMMAE[44]

End point description:

PK of pola-related analyte acMMAE was measured. Cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts. Here, 9999= data is not evaluable as the samples were below lower limit of quantification (BLLQ); 99999= Since only 1 participant was analysed, the geometric coefficient of variation was not calculated; 999999= participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants Phase Ib and Phase II who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoint. Cycle=C, Day = D, Post dose= Pd.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2: pre-dose and 30 minutes (min) post dose; Cycle 1 Days 8 and 15; Cycle 2 and 4 Day 1: pre-dose and 30 min post dose; unscheduled visits: pre-dose and 30 min post dose; study treatment completion (up to approximately 84 months)

Notes:

[44] - 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: No descriptive statistics were planned for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=6,6,6,36,36,17,16)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D2: 30 min Pd (n=6,6,6,36,35,18,19)	654 (± 29.3)	617 (± 26.2)	719 (± 26.7)	718 (± 14.2)
C1 D8 (n=5,6,6,6,0,0,0,0)	29.4 (± 5887.2)	75.9 (± 40.8)	90.7 (± 46.1)	109 (± 48.2)
C1 D15 (n=5,6,5,6,0,0,0,0)	12.2 (± 1626.9)	25.4 (± 29.8)	28.9 (± 48.6)	34.4 (± 37.3)
C2 D1: Pre-dose (n=6,6,6,35,33,18,16)	3.21 (± 546.5)	12.4 (± 47.9)	8.75 (± 77.7)	16.6 (± 25.6)
C2 D1: 30 min Pd (n=6,6,6,6,0,0,0,0)	685 (± 22.0)	683 (± 20.1)	803 (± 20.1)	834 (± 13.5)
C4 D1: Pre-dose (n=5,3,6,4,31,23,16,12)	12.2 (± 26.1)	21.1 (± 46.7)	15.3 (± 61.9)	26.2 (± 22.1)
C4 D1: 30 min Pd (n=5,3,6,4,29,23,17,12)	748 (± 23.4)	754 (± 14.4)	734 (± 22.0)	716 (± 13.7)
Unscheduled Visit (n=0,0,0,0,0,3,2,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit: Pre-dose (n=0,0,0,0,1,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit:30min Pd(n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Study Treatment Completion (n=0,0,1,0,28,27,14,8)	999999 (± 999999)	999999 (± 999999)	18.7 (± 99999)	999999 (± 999999)

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	36	18	19
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=6,6,6,36,36,17,16)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D2: 30 min Pd (n=6,6,6,36,35,18,19)	492 (± 241.6)	643 (± 24.7)	453 (± 682.8)	472 (± 617.2)
C1 D8 (n=5,6,6,6,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C1 D15 (n=5,6,5,6,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C2 D1: Pre-dose (n=6,6,6,35,33,18,16)	4.72 (± 159.8)	12.7 (± 120.5)	9.05 (± 74.4)	13.1 (± 45.2)
C2 D1: 30 min Pd (n=6,6,6,6,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C4 D1: Pre-dose (n=5,3,6,4,31,23,16,12)	11.2 (± 109.3)	20.7 (± 46.4)	15.2 (± 30.5)	19.6 (± 30.5)
C4 D1: 30 min Pd (n=5,3,6,4,29,23,17,12)	689 (± 20.9)	645 (± 21.4)	829 (± 20.3)	709 (± 10.1)
Unscheduled Visit (n=0,0,0,0,0,3,2,0)	999999 (± 999999)	41.1 (± 49.4)	53.0 (± 58.0)	999999 (± 999999)
Unscheduled Visit: Pre-dose (n=0,0,0,0,1,1,0,0)	1.21 (± 99999)	0.180 (± 99999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit:30min Pd(n=0,0,0,0,0,1,0,0)	999999 (± 999999)	915 (± 99999)	999999 (± 999999)	999999 (± 999999)
Study Treatment Completion (n=0,0,1,0,28,27,14,8)	10.7 (± 181.7)	14.2 (± 95.7)	14.9 (± 69.4)	12.3 (± 109.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G (Phase II NF Cohort): Percentage of Participants with OR at PRA Based on CT only as Determined by IRC

End point title	Arm G (Phase II NF Cohort): Percentage of Participants with OR at PRA Based on CT only as Determined by IRC

End point description:

OR at PRA=percentage of participants with CR or PR at the PRA, as assessed by the IRC perMLRC. Per MLRC, CR based on CT =complete radiologic response in lymph nodes and ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi and no ELS of disease organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, IHC negative. PR per CT only = partial remission in lymph nodes and ELS with ≥50% decrease in SPD of up to 6 target measurable lymph nodes and extranodal sites, absent/normal/regressed but with no increase in non-measured lesions, spleen regressing by ≥50% in length beyond normal it, no new sites of lesions. ITT population included all randomised participants in Arm G irrespective of whether or not they received the study treatment. Values have been rounded off to the nearest whole number. The analysis was done 6-8 weeks after Cycle 6 Day 1 (each cycle=21 days for DLBCL cohorts).

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to 23 weeks)

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (confidence interval 95%)	33.3 (19.57 to 49.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G (Phase II NF Cohort): Percentage of Participants with OR at PRA Based on CT only as Determined by Investigator

End point title	Arm G (Phase II NF Cohort): Percentage of Participants with OR at PRA Based on CT only as Determined by Investigator

End point description:

OR at PRA=percentage of participants with CR/PR at the PRA, as assessed by the investigator based on MLRC. Per MLRC, CR based on CT=complete radiologic response in lymph nodes and ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi and no ELS of disease organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, IHC negative. PR per CT only = partial remission in lymph nodes and ELS with ≥50% decrease in SPD of up to 6 target measurable lymph nodes and extranodal sites, absent/normal/regressed but with no increase in non-measured lesions, spleen regressing by ≥50% in length beyond normal it, no new sites of lesions. ITT population included all randomised participants in Arm G irrespective of whether or not they received the study treatment. Values have been rounded off to the nearest whole number. The analysis was done 6-8 weeks after Cycle 6 Day 1 (each cycle=21 days for DLBCL cohorts).

End point type	Secondary

End point timeframe:

6 to 8 weeks after Cycle 6 Day 1 (cycle length is 21 days for DLBCL cohorts) or last dose of study drug (up to approximately 23 weeks)

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (confidence interval 95%)	38.1 (23.57 to 54.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G+H (Phase II NF Cohorts): Plasma Concentration of Polatuzumab Vedotin Analyte: acMMAE

End point title	Arm G+H (Phase II NF Cohorts): Plasma Concentration of Polatuzumab Vedotin Analyte: acMMAE

End point description:

PK of one pola-related analytes: acMMAE was measured. Cycle length is 21 days for DLBCL cohorts. PK evaluable population included all the ITT participants in Arm G+H (Phase II NF Cohort) who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2: post dose; Cycle 2 and 4 Day 1: pre-dose and post dose

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	102			
Units: ng/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 2: Post Dose (n=102)	653 (± 237)			
Cycle 2 Day 1: Pre-dose (n=94)	14.6 (± 8.66)			
Cycle 2 Day 1: Post Dose (n=92)	667 (± 155)			
Cycle 4 Day 1: Pre-dose (n=61)	23.2 (± 8.59)			
Cycle 4 Day 1: Post Dose (n=60)	659 (± 156)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of of Polatuzumab Vedotin Analyte: Total Ab

End point title	Serum Concentration of of Polatuzumab Vedotin Analyte: Total Ab[45]

End point description:

PK of pola-related analyte Total Ab was measured. Cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts. Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since only 1

participant was analysed, the geometric coefficient of variation was not calculated; 999999= participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants who received at least one study treatment and who provided suitable PK samples. Overall Number Analysed are the number of participants with data available for analysis. 'Number Analysed is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Cycle 1 Days 2: pre-dose & 30 min post dose; Cycle 1 Days 8 & 15; Cycle 2 and 4 Day 1 and unscheduled visits: pre-dose & 30 min post dose; Follow up at Day 1: Months 3, 6, 12, 18 & 24; study treatment completion visit (up to approx. 84 months)

Notes:

[45] - 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: No descriptive statistics were planned for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: grams per milliliters (g/mL)				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=6,6,6,6,36,36,17,18)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D2: 30 min Pd (n=6,6,6,6,36,35,18,19)	33.2 (± 28.4)	36.6 (± 25.4)	37.5 (± 29.1)	34.3 (± 20.3)
C1 D8 (n=5,6,66,0,0,0,0)	3.43 (± 4393.4)	9.01 (± 43.7)	10.2 (± 39.3)	10.0 (± 31.9)
C1 D15 (n=5,6,66,0,0,0,0)	1.83 (± 1784.3)	4.26 (± 35.3)	4.61 (± 40.6)	5.22 (± 28.4)
C2 D1: Pre-dose (n=6, 6,6,36,33,18,16)	0.696 (± 941.2)	2.31 (± 54.2)	2.20 (± 76.1)	3.70 (± 27.4)
C2 D1: 30 min Pd (n=6,6,6,6,0,0,0,0)	35.8 (± 25.9)	39.5 (± 28.3)	43.4 (± 31.1)	42.2 (± 22.9)
C4 D1: Pre-dose (n=5,3,6,4,32,23,16,12)	3.44 (± 30.5)	5.03 (± 59.0)	4.61 (± 62.2)	6.26 (± 18.3)
C4 D1: 30 min Pd (n=5,3,6,4,31,23,17,12)	40.2 (± 27.2)	44.6 (± 11.0)	43.0 (± 25.8)	47.1 (± 24.2)
Follow up on Month 3, Day 1 (n=5,3,5,2,23,18,15,8)	0.164 (± 51.9)	0.771 (± 193.4)	0.910 (± 82.8)	0.394 (± 27.1)
Follow up on Month 6, Day 1 (n=5,3,5,2,21,12,10,7)	0.0250 (± 0.0)	0.0788 (± 230.0)	0.219 (± 96.6)	0.104 (± 18.5)
Follow up on Month 12, Day 1 (n=4,3,4,3,13,9,6,3)	0.0250 (± 0.0)	0.0250 (± 0.0)	0.0298 (± 35.9)	0.0250 (± 0.0)
Follow up on Month 18, Day 1 (n=2,3,2,2,2,3, 3,3)	0.0250 (± 0.0)	0.0250 (± 0.0)	0.0250 (± 0.0)	0.0250 (± 0.0)
Follow up on Month 24, Day 1 (n=2,3,1,1,0,0,0,1)	0.0250 (± 0.0)	0.0250 (± 0.0)	0.0250 (± 99999)	0.0250 (± 99999)
Unscheduled Visit (n=3,2,0,1,0,4,3,0)	0.0250 (± 0.0)	0.0250 (± 0.0)	999999 (± 999999)	0.0250 (± 99999)
Unscheduled Visit: Pre-dose (n=0,0,0,0,1,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit: 30 min Pd (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Treatment Completion Visit (n=0,0,1,0,27,27,14,8)	999999 (± 999999)	999999 (± 999999)	5.34 (± 999999)	999999 (± 999999)

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	36	18	19
Units: grams per milliliters (g/mL)				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=6,6,6,6,36,36,17,18)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D2: 30 min Pd (n=6,6,6,6,36,35,18,19)	35.4 (± 27.7)	34.6 (± 26.2)	32.4 (± 22.8)	38.3 (± 20.3)
C1 D8 (n=5,6,66,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C1 D15 (n=5,6,66,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C2 D1: Pre-dose (n=6, 6,6,36,33,18,16)	1.23 (± 203.1)	2.48 (± 137.6)	2.20 (± 100.6)	2.83 (± 41.8)
C2 D1: 30 min Pd (n=6,6,6,6,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C4 D1: Pre-dose (n=5,3,6,4,32,23,16,12)	3.61 (± 97.8)	5.72 (± 39.9)	4.82 (± 20.8)	5.03 (± 29.3)
C4 D1: 30 min Pd (n=5,3,6,4,31,23,17,12)	44.8 (± 24.3)	40.6 (± 20.6)	55.0 (± 21.3)	37.5 (± 11.6)
Follow up on Month 3, Day 1 (n=5,3,5,2,23,18,15,8)	0.265 (± 209.9)	0.316 (± 266.2)	0.489 (± 174.2)	0.543 (± 126.7)
Follow up on Month 6, Day 1 (n=5,3,5,2,21,12,10,7)	0.0539 (± 145.7)	0.0564 (± 195.7)	0.0920 (± 123.5)	0.150 (± 206.6)
Follow up on Month 12, Day 1 (n=4,3,4,3,13,9,6,3)	0.0250 (± 0.0)	0.0301 (± 60.6)	0.0250 (± 0.0)	0.0250 (± 0.0)
Follow up on Month 18, Day 1 (n=2,3,2,2,2,3, 3,3)	0.0250 (± 0.0)	0.0250 (± 0.0)	0.0250 (± 0.0)	0.0250 (± 0.0)
Follow up on Month 24, Day 1 (n=2,3,1,1,0,0,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	0.0250 (± 99999)
Unscheduled Visit (n=3,2,0,1,0,4,3,0)	999999 (± 999999)	1.65 (± 5419.8)	1.23 (± 30267.8)	999999 (± 999999)
Unscheduled Visit: Pre-dose (n=0,0,0,0,1,1,0,0)	0.279 (± 99999)	0.0250 (± 99999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit: 30 min Pd (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	42.0 (± 99999)	999999 (± 999999)	999999 (± 999999)
Treatment Completion Visit (n=0,0,1,0,27,27,14,8)	3.34 (± 180.5)	4.33 (± 69.4)	4.57 (± 57.2)	3.23 (± 79.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G+H (Phase II NF Cohorts): Plasma Concentration of Polatuzumab Vedotin Analyte: Total Ab

End point title	Arm G+H (Phase II NF Cohorts): Plasma Concentration of Polatuzumab Vedotin Analyte: Total Ab

End point description:

PK of pola-related analyte: Total Ab was measured. Cycle length is 21 days for DLBCL cohorts. PK evaluable population included all the ITT participants in Arm G+H (Phase II NF Cohort) who received at least one study treatment and who provided suitable PK samples. Overall Number Analysed are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2: post dose; Cycle 2 and 4 Day 1: pre-dose and post dose

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	103			
Units: ng/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 2: Post Dose (n=103)	33.9 (± 11.7)			
Cycle 2 Day 1: Pre-dose (n=94)	3.27 (± 4.37)			
Cycle 2 Day 1: Post Dose (n=92)	36.0 (± 8.71)			
Cycle 4 Day 1: Pre-dose (n=63)	5.41 (± 1.79)			
Cycle 4 Day 1: Post Dose (n=61)	39.2 (± 7.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of Polatuzumab Vedotin Analyte: Unconjugated MMAE

End point title	Plasma Concentration of Polatuzumab Vedotin Analyte: Unconjugated MMAE[46]

End point description:

PK of pola-related analytes unconjugated MMAE was measured. Cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts. Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since only 1 participant was analyzed, the geometric coefficient of variation was not calculated; 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants Phase Ib and Phase II who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2: pre-dose and 30 min post dose, Cycle 1 Days 8 and 15; Cycles 2 and 4: pre-dose and 30 min post dose; unscheduled visits: pre-dose and 30 min post dose; study treatment completion (up to approximately 84 months)

Notes:

[46] - 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: No descriptive statistics were planned for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=6,6,6,6,35,36,17,17)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D2: 30 min Pd (n=6,6,6,6,36,3,18,18)	0.726 (± 297.5)	0.234 (± 80.2)	0.397 (± 67.7)	0.327 (± 41.4)
C1 D8 (n=5,6,6,6,0,0,0,0)	1.48 (± 100.8)	1.84 (± 78.4)	1.96 (± 51.5)	2.34 (± 21.4)
C1 D15 (n=5,6,5,6,0,0,0,0)	0.311 (± 93.8)	0.531 (± 88.5)	0.705 (± 60.0)	0.688 (± 19.5)
C2 D1: Pre-dose (n=6,6,6,6,35,33,17,15)	0.0264 (± 70.8)	0.158 (± 79.4)	0.0512 (± 129.3)	0.150 (± 44.4)
C2 D1: 30 min Pd (n=6,6,6,6,0,0,0,0)	0.185 (± 54.2)	0.263 (± 72.7)	0.231 (± 53.5)	0.345 (± 31.9)
C4 D1: Pre-dose (n=5,3,6,4,32,23,15,12)	0.0414 (± 102.9)	0.133 (± 72.6)	0.0511 (± 68.3)	0.150 (± 44.3)
C4 D1: 30 min Pd (n=4,3,6,4,29,23,15,12)	0.234 (± 35.0)	0.266 (± 27.0)	0.167 (± 39.2)	0.257 (± 32.3)
Unscheduled Visit (n=0,0,0,0,0,0,2,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit: Pre-dose (n=0,0,0,0,1,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit: 30 min Pd (n=0,0,0,0,1,01,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Treatment Completion (n=0,0,1,0,28,27,13,8)	999999 (± 999999)	999999 (± 999999)	0.0595 (± 99999)	999999 (± 999999)

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	36	18	18
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=6,6,6,6,35,36,17,17)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D2: 30 min Pd (n=6,6,6,6,36,3,18,18)	0.402 (± 80.2)	0.315 (± 105.3)	0.243 (± 101.8)	0.456 (± 103.1)
C1 D8 (n=5,6,6,6,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C1 D15 (n=5,6,5,6,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C2 D1: Pre-dose (n=6,6,6,6,35,33,17,15)	0.0373 (± 81.5)	0.159 (± 80.9)	0.0451 (± 76.9)	0.186 (± 86.8)
C2 D1: 30 min Pd (n=6,6,6,6,0,0,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
C4 D1: Pre-dose (n=5,3,6,4,32,23,15,12)	0.0554 (± 77.3)	0.158 (± 58.2)	0.0481 (± 83.2)	0.141 (± 102.3)
C4 D1: 30 min Pd (n=4,3,6,4,29,23,15,12)	0.198 (± 32.0)	0.316 (± 38.9)	0.195 (± 38.1)	0.283 (± 56.9)

Unscheduled Visit (n=0,0,0,0,0,0,2,0)	999999 (± 999999)	999999 (± 999999)	0.738 (± 64.6)	999999 (± 999999)
Unscheduled Visit: Pre-dose (n=0,0,0,0,1,1,0,0)	0.0180 (± 99999)	0.0180 (± 99999)	999999 (± 999999)	999999 (± 999999)
Unscheduled Visit: 30 min Pd (n=0,0,0,0,1,01,0,0)	999999 (± 999999)	0.114 (± 99999)	999999 (± 999999)	999999 (± 999999)
Treatment Completion (n=0,0,1,0,28,27,13,8)	0.0506 (± 113.0)	0.0749 (± 165.9)	0.0682 (± 110.4)	0.150 (± 179.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Arm G+H (Phase II NF Cohorts): Plasma Concentration of Polatuzumab Vedotin Analyte: Unconjugated MMAE

End point title	Arm G+H (Phase II NF Cohorts): Plasma Concentration of Polatuzumab Vedotin Analyte: Unconjugated MMAE

End point description:

PK of one pola-related analytes: Unconjugated MMAE was measured. Cycle length is 21 days for DLBCL cohorts. PK evaluable population included all the ITT participants in Arm G+H (Phase II NF Cohort) who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2: post dose; Cycle 1 and 3 Day 8 and 15; Cycle 2, 3 and 4 Day 1: pre-dose and post dose

End point values	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	103			
Units: ng/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 2: Post Dose (n=103)	0.590 (± 1.08)			
Cycle 2 Day 1: Pre-dose (n=94)	0.229 (± 0.248)			
Cycle 2 Day 1: Post Dose (n=91)	0.316 (± 0.213)			
Cycle 4 Day 1: Pre-dose (n=61)	0.186 (± 0.118)			
Cycle 4 Day 1: Post Dose (n=60)	0.256 (± 0.118)			

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of Bendamustine

End point title	Plasma Concentration of Bendamustine[47]

End point description:

Cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts. As pre specified in the protocol plasma concentration of bendamustine was not assessed in the Phase II NF Cohort (Arm G+H). Here, 9999= data is not evaluable as the samples were BLLQ. PK evaluable population included all the ITT participants who Phase Ib and Phase II received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2: pre-dose, 5 min, 1 hour (h); 2h, 3h and 4h post dose

Notes:

[47] - 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: No descriptive statistics were planned for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[48]	0[49]	0[50]	0[51]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=0,0,0,0,37,39,34,33,18,19)	()	()	()	()
C1 D2: 5 min Pd (n=0,0,0,0,35,38,35,31,18,19)	()	()	()	()
C1 D2: 1h Pd (n=0,0,0,0,35,39,34,31,17,18)	()	()	()	()
C1 D2: 2h Pd (n=0,0,0,0,34,39,34,333,17,16)	()	()	()	()
C1 D2: 3h Pd (n=0,0,0,0,33,38,34,332,17,15)	()	()	()	()
C1 D2: 4h Pd (n=0,0,0,0,31,37,31,333,17,15)	()	()	()	()

Notes:

[48] - Participants were not analysed for this PK endpoint.

[49] - Participants were not analysed for this PK endpoint.

[50] - Participants were not analysed for this PK endpoint.

[51] - Participants were not analysed for this PK endpoint.

End point values	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	39	35	33
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=0,0,0,0,37,39,34,33,18,19)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

C1 D2: 5 min Pd (n=0,0,0,0,35,38,35,31,18,19)	2130 (± 665.6)	2810 (± 222.7)	2740 (± 550.9)	1700 (± 1865.5)
C1 D2: 1h Pd (n=0,0,0,0,35,39,34,31,17,18)	456 (± 167.8)	353 (± 187.9)	518 (± 154.2)	451 (± 380.2)
C1 D2: 2h Pd (n=0,0,0,0,34,39,34,333,17,16)	84.4 (± 173.5)	55.1 (± 236.5)	93.8 (± 250.5)	101 (± 375.8)
C1 D2: 3h Pd (n=0,0,0,0,33,38,34,332,17,15)	20.5 (± 220.1)	12.7 (± 246.4)	23.5 (± 461.0)	21.5 (± 509.9)
C1 D2: 4h Pd (n=0,0,0,0,31,37,31,333,17,15)	7.60 (± 278.5)	4.58 (± 268.4)	8.11 (± 724.8)	8.08 (± 615.9)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	19		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D2: Pre-dose (n=0,0,0,0,37,39,34,33,18,19)	9999 (± 9999)	9999 (± 9999)		
C1 D2: 5 min Pd (n=0,0,0,0,35,38,35,31,18,19)	3090 (± 68.3)	3790 (± 119.4)		
C1 D2: 1h Pd (n=0,0,0,0,35,39,34,31,17,18)	478 (± 111.4)	639 (± 165.6)		
C1 D2: 2h Pd (n=0,0,0,0,34,39,34,333,17,16)	62.8 (± 104.3)	128 (± 196.7)		
C1 D2: 3h Pd (n=0,0,0,0,33,38,34,332,17,15)	12.4 (± 132.0)	28.2 (± 287.4)		
C1 D2: 4h Pd (n=0,0,0,0,31,37,31,333,17,15)	3.30 (± 147.2)	6.18 (± 131.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Rituximab

End point title	Serum Concentration of Rituximab[52]

End point description:

Cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts. As pre specified in the protocol serum concentration of rituximab was not assessed in the Phase II NF Cohort (Arm G+H). Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since only 1 participant was analyzed, the geometric coefficient of variation was not calculated; 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1a (Phase Ib) and Arms A-D (Phase II) who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Cycle 1 Days 1: pre-dose and 30 min post dose; Cycle 2 and 4 Day 1: pre-dose; unscheduled visits: pre-dose and 30 min post dose (up to approximately 84 months)

Notes:

[52] - 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: No descriptive statistics were planned for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Arm A (Phase II Randomisation): Pola+BR in FL	Arm B (Phase II Randomisation): BR in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[53]	0[54]	37	38
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Pre-dose (n=0,0,37,38,34,34)	()	()	9999 (± 9999)	9999 (± 9999)
C1 D1: 30 min Pd (n=0,0,32,38,34,33)	()	()	182 (± 27.2)	202 (± 24.5)
C2 D1: Pre-dose (n=0,0,36,33,29,27)	()	()	22.8 (± 79.2)	20.2 (± 145.9)
C 4 D1: Pre-dose (n=0,0,31,33,21,14)	()	()	65.1 (± 46.5)	62.3 (± 42.7)
Unscheduled: Pre-dose (n=0,0,2,0,1,1)	()	()	30.6 (± 118.0)	999999 (± 999999)
Unscheduled: 30 min Pd (n=0,0,0,0,0,1)	()	()	999999 (± 999999)	999999 (± 999999)

Notes:

[53] - Participants were not analysed for this PK endpoint.

[54] - Participants were not analysed for this PK endpoint.

End point values	Arm C (Phase II Randomisation): Pola+BR in DLBCL	Arm D (Phase II Randomisation): BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	34		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Pre-dose (n=0,0,37,38,34,34)	9999 (± 9999)	9999 (± 9999)		
C1 D1: 30 min Pd (n=0,0,32,38,34,33)	188 (± 19.9)	180 (± 18.0)		
C2 D1: Pre-dose (n=0,0,36,33,29,27)	34.9 (± 89.9)	34.6 (± 69.7)		
C 4 D1: Pre-dose (n=0,0,31,33,21,14)	74.7 (± 50.9)	83.3 (± 49.1)		
Unscheduled: Pre-dose (n=0,0,2,0,1,1)	298 (± 99999)	2.00 (± 99999)		
Unscheduled: 30 min Pd (n=0,0,0,0,0,1)	999999 (± 999999)	165 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Obinutuzumab

End point title	Serum Concentration of Obinutuzumab[55]

End point description:

Cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts. Here, 9999= data is not evaluable

as the samples were BLLQ; 99999= Since only 1 participant was analysed, the geometric coefficient of variation was not calculated; 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1b (Phase 1b) and Arms E and F (Phase II) who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Cycles 1 and 4 Days 1: pre-dose and 30 min post dose; Cycle 2 Day1: pre-dose; Follow up visits on Day 1: Months 3, 6, 12, 18 and 24; unscheduled visits: pre-dose and 30 min post dose; study treatment completion (up to approximately 84 months)

Notes:

[55] - 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: No descriptive statistics were planned for this endpoint.

End point values	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	19	19
Units: g/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Pre-dose (6,5,19,19)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D1: 30 min Pd (n=0,0,14,13)	999999 (± 999999)	999999 (± 999999)	341 (± 22.1)	221 (± 105.5)
C2 D1: Pre-dose (n=6,6,18,17)	283 (± 38.4)	412 (± 40.8)	301 (± 39.3)	349 (± 58.0)
C4 D1: Pre-dose (n=6,4,17,12)	293 (± 53.8)	359 (± 28.9)	291 (± 37.9)	290 (± 36.4)
C4 D1: 30 min Pd (n=0,0,16,12)	999999 (± 999999)	999999 (± 999999)	701 (± 27.4)	642 (± 29.5)
Follow up on Month 3, D1 (n=5,2,16,8)	67.7 (± 47.8)	28.8 (± 17.0)	38.5 (± 167.8)	55.1 (± 119.9)
Follow up on Month 6, D1 (n=5,2,10,7)	11.5 (± 56.6)	5.38 (± 12.4)	7.64 (± 412.2)	15.8 (± 137.6)
Follow up on Month 12, D1 (n=4,3,6,2)	0.237 (± 717.6)	0.389 (± 119.3)	0.162 (± 569.7)	0.732 (± 18.7)
Follow up on Month 18, D1 (n=2,2,7,3)	0.00978 (± 1188.5)	0.0107 (± 170.5)	0.00842 (± 347.4)	0.0460 (± 86.9)
Follow up on Month 24, D1 (n=1,1,0,1)	0.00203 (± 99999)	0.00203 (± 99999)	99999 (± 99999)	0.00203 (± 99999)
Unscheduled (n=0,1,1,0)	999999 (± 999999)	3.09 (± 99999)	20.8 (± 999999)	999999 (± 999999)
Unscheduled Visit: Pre-dose (n=0,0,0,1)	999999 (± 999999)	999999 (± 999999)	99999 (± 99999)	0.0626 (± 99999)
Unscheduled Visit: 30 min Pd (n=0,0,0,1)	999999 (± 999999)	999999 (± 999999)	99999 (± 99999)	349 (± 99999)
Treatment Completion Visit (n=1,0,14,8)	367 (± 99999)	999999 (± 999999)	242 (± 52.7)	232 (± 46.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Cmax of Polatuzumab Vedotin, Bendamustine, and Rituximab

in Cohort 1a

End point title	Phase Ib: Cmax of Polatuzumab Vedotin, Bendamustine, and Rituximab in Cohort 1a[56]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1a (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema Cmax was not evaluated for Bendamustine and Rituximab.

End point type	Secondary

End point timeframe:

Cycles 1, 2 and 4 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[56] - 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 only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: ng/mL				
arithmetic mean (standard deviation)				
acMMAE: Cycle 1 (n=6,6)	676 (± 176)	634 (± 158)		
acMMAE: Cycle 2 (n=6,6)	697 (± 129)	694 (± 138)		
acMMAE: Cycle 4 (n=5,3)	763 (± 159)	759 (± 107)		
Total Ab: Cycle 1 (n=6,6)	34.3 (± 8.57)	37.6 (± 9.42)		
Total Ab: Cycle 2 (n=6,6)	36.6 (± 8.00)	40.6 (± 9.46)		
Total Ab: Cycle 4 (n=5,3)	41.3 (± 9.98)	44.8 (± 5.06)		
Unconjugated MMAE: Cycle 1 (n=6,6)	3.31 (± 4.00)	2.21 (± 1.34)		
Unconjugated MMAE: Cycle 2 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 1 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 2 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab: Cycle 1(n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab: Cycle 2 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Cmax of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1b

End point title	Phase Ib: Cmax of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1b[57]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1b (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema Cmax was not evaluated for Bendamustine and Obinutuzumab.

End point type	Secondary

End point timeframe:

Cycles 1, 2 and 4 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[57] - 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 only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: ng/mL				
arithmetic mean (standard deviation)				
acMMAE: Cycle 1 (n=6,6)	738 (± 165)	725 (± 104)		
acMMAE: Cycle 2 (n=6,6)	816 (± 168)	841 (± 115)		
acMMAE: Cycle 4 (n=6,4)	749 (± 158)	721 (± 97.7)		
Total Ab: Cycle 1 (n=6,6)	38.7 (± 9.84)	34.9 (± 7.52)		
Total Ab: Cycle 2 (n=6,6)	45.0 (± 12.1)	43.1 (± 9.52)		
Total Ab: Cycle 4 (n=6,4)	44.2 (± 11.2)	48.2 (± 12.5)		
Unconjugated MMAE: Cycle 1 (n=6,6)	2.17 (± 1.08)	2.39 (± 0.492)		
Unconjugated MMAE: Cycle 2 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 1 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 2(n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab: Cycle 1 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab: Cycle 2 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Cmax of Polatuzumab Vedotin, Bendamustine, and Rituximab in Arms A and C

End point title	Phase II: Cmax of Polatuzumab Vedotin, Bendamustine, and Rituximab in Arms A and C[58]

End point description:

PK of three pola analytes: acMMAE, total antibody and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms A and C who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1; Cycle 4 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[58] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	35		
Units: ng/mL				
arithmetic mean (standard deviation)				
acMMAE: Cycle 1 (n=36,35)	622 (± 194)	661 (± 149)		
acMMAE: Cycle 4 (n=29,23)	703 (± 150)	659 (± 135)		
Total Ab: Cycle 1 (n=36,35)	36.7 (± 9.54)	35.7 (± 8.50)		
Total Ab: Cycle 4 (n=31,23)	46.1 (± 11.4)	41.4 (± 8.29)		
Unconjugated MMAE: Cycle 1 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 1 (n=34,33)	3.57 (± 2.06)	4.23 (± 2.26)		
Bendamustine: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab: Cycle 1 (n=32,34)	188 (± 49.2)	191 (± 35.9)		
Rituximab: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Cmax of Bendamustine and Rituximab in Arms B and D

End point title	Phase II: Cmax of Bendamustine and Rituximab in Arms B and D[59]

End point description:

PK evaluable population included all the ITT participants in Arms B and D who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[59] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm B (Phase II Randomisation) : BR in FL	Arm D (Phase II Randomisation) : BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	33		
Units: ug/mL				
arithmetic mean (standard deviation)				
Bendamustine (n=34,30)	3.21 (± 2.09)	3.85 (± 2.91)		
Rituximab (n=33,34)	207 (± 50.1)	183 (± 33.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Cmax of Polatuzumab Vedotin, Obinutuzumab and Bendamustine in Arms E and F

End point title	Phase II: Cmax of Polatuzumab Vedotin, Obinutuzumab and Bendamustine in Arms E and F[60]

End point description:

PK of three pola-related analytes: acMMAE, unconjugated MMAE and total antibody were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms E and F who received at least one study treatment and who provided suitable PK samples. Overall Number Analysed are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1; Cycle 4 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[60] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	19		
Units: ug/mL				
arithmetic mean (standard deviation)				
acMMAE: Cycle 1 (n=18,19)	692 (± 230)	703 (± 211)		
acMMAE: Cycle 4 (n=17,12)	845 (± 165)	713 (± 70.6)		
Total Ab: Cycle 1 (n=18,19)	33.3 (± 8.04)	39.0 (± 7.63)		
Total Ab: Cycle 4 (n=17,12)	56.1 (± 11.2)	37.8 (± 4.51)		
Unconjugated MMAE: Cycle 1 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine: Cycle 1 (n=16,19)	3.30 (± 1.58)	5.47 (± 4.30)		
Bendamustine: Cycle 4 (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Obinutuzumab: Cycle 1 (n=14,13)	349 (± 72.8)	274 (± 118)		
Obinutuzumab: Cycle 4 (n=16,12)	727 (± 217)	666 (± 190)		

Statistical analyses

No statistical analyses for this end point

Secondary: Arm H (Phase II NF Cohort): Cmax of Polatuzumab Vedotin (Lyophilized)

End point title	Arm H (Phase II NF Cohort): Cmax of Polatuzumab Vedotin (Lyophilized)

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. As pre-specified in the protocol the analysis of this endpoint was based on sponsor's discretion however, sponsor opted to not collect data for this endpoint.

End point type	Secondary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4,(cycle length is 21 days for DLBCL cohorts) up to approximately 9 weeks

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	0[61]			
Units: nanograms per milliliters (ng/mL)				
geometric mean (geometric coefficient of variation)	()			

Notes:

[61] - Data was not collected for this endpoint per the sponsor's discretion.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: AUC from Time Zero to Infinity (AUCinf) of Polatuzumab Vedotin, Bendamustine, and Rituximab in Cohort 1a

End point title	Phase Ib: AUC from Time Zero to Infinity (AUCinf) of Polatuzumab Vedotin, Bendamustine, and Rituximab in Cohort 1a[62]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. The unit of measure for AUC is day*micrograms per millilitres (day*ug/mL]). Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1a (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Overall number analysed' is the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema AUC was not evaluated for bendamustine and rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[62] - 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 only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	6		
Units: day*ug/mL				
geometric mean (geometric coefficient of variation)				
acMMAE (n=4,6)	2830 (± 12.1)	2110 (± 28.4)		
Total Ab (n=4,6)	298 (± 4.9)	214 (± 35.9)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: AUCinf of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1b

End point title	Phase Ib: AUCinf of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1b[63]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1b (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema AUC was not evaluated for bendamustine and obinutuzumab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[63] - 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 only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: day*ug/mL				
geometric mean (geometric coefficient of variation)				
acMMAE (n=5,6)	2600 (± 34.4)	2650 (± 16.4)		
Total Ab (n=6,6)	267 (± 30.2)	252 (± 21.6)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Obinutuzumab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: AUCinf of Polatuzumab Vedotin, Bendamustine, and Rituximab in Arms A and C

End point title	Phase II: AUCinf of Polatuzumab Vedotin, Bendamustine, and Rituximab in Arms A and C[64]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms A and C who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema AUC was not evaluated for pola and rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[64] - 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 only for Arms A and C, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	30		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
acMMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Total Ab (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=31,30)	3.29 (± 73.3)	3.62 (± 78.5)		
Rituximab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: AUCinf of Bendamustine and Rituximab in Arms B and D

End point title	Phase II: AUCinf of Bendamustine and Rituximab in Arms B and D[65]

End point description:

Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms B and D who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema AUC was not evaluated for rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[65] - 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 only for arms B and D, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm B (Phase II Randomisation): BR in FL	Arm D (Phase II Randomisation): BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	29		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Bendamustine (n=33,29) Rituximab (n=0,0)	2.86 (± 67.3) 999999 (± 999999)	3.43 (± 97.4) 999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: AUCinf of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Arms E and F

End point title	Phase II: AUCinf of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Arms E and F[66]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms E and F who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema AUC was not evaluated for pola and obinutuzumab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[66] - 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 only for arms E and F, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	14		
Units: h*ug/mL				
geometric mean (geometric coefficient				

of variation)				
acMMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Total Ab (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=15,14)	2.88 (± 28.9)	4.10 (± 67.4)		
Obinutuzumab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: CL of Polatuzumab Vedotin, Bendamustine, and Rituximab in Cohort 1a

End point title	Phase Ib: CL of Polatuzumab Vedotin, Bendamustine, and Rituximab in Cohort 1a[67]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1a (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Overall number analysed' is the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema CL was not evaluated for bendamustine and rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[67] - 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 only for Phase Ia cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	6		
Units: mL/day/kg				
geometric mean (geometric coefficient of variation)				
acMMAE (n=4,6)	11.3 (± 12.9)	15.2 (± 27.9)		
Total Ab (n=4,6)	6.05 (± 4.7)	8.48 (± 35.2)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Arm H (Phase II NF Cohort): AUC of Polatuzumab Vedotin (Lyophilized)

End point title	Arm H (Phase II NF Cohort): AUC of Polatuzumab Vedotin (Lyophilized)

End point description:

PK of three pola-related analytes: antibody acMMAE, total antibody, and unconjugated MMAE were measured. As pre-specified in the protocol the analysis of this endpoint was based on sponsor's discretion however, sponsor opted to not collect data for this endpoint.

End point type	Secondary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4, (each cycle is 21 days DLBCL cohorts) up to approximately 9 weeks

End point values	Arm H (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	0[68]			
Units: ng*day/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[68] - Data was not collected for this endpoint per the sponsor's discretion.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: CL of Polatuzumab vedotin, Bendamustine, and Obinutuzumab in Cohort 1b

End point title	Phase Ib: CL of Polatuzumab vedotin, Bendamustine, and Obinutuzumab in Cohort 1b[69]

End point description:

PK of three polatuzumab vedotin-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1b (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema CL was not evaluated for bendamustine and obinutuzumab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[69] - 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 only for Phase Ia cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: mL/day/kg				
geometric mean (geometric coefficient of variation)				
acMMAE (n=5,6)	12.3 (± 34.9)	12.1 (± 17.0)		
Total Ab (n=6,6)	6.76 (± 30.6)	7.17 (± 22.2)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Obinutuzumab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: CL of Polatuzumab Vedotin, Bendamustine and Rituximab in Arms A and C

End point title	Phase II: CL of Polatuzumab Vedotin, Bendamustine and Rituximab in Arms A and C[70]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms A and B who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema CL was not evaluated for pola and rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[70] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: Liters per hour (L/h)				
geometric mean (geometric coefficient of variation)				
acMMAE(n=0,0)	999999 (± 999999)	999999 (± 999999)		
Total Ab (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=30,29)	47.9 (± 60.8)	42.6 (± 66.4)		
Rituximab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: CL of Bendamustine and Rituximab in Arms B and D

End point title	Phase II: CL of Bendamustine and Rituximab in Arms B and

End point description:

PK evaluable population included all the ITT participants in Arms B and D who received at least one study treatment and who provided suitable PK samples. Overall Number Analysed are the number of participants with data available for analysis. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema CL was not evaluated for rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[71] - 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 only for arms B and D hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm B (Phase II Randomisation) : BR in FL	Arm D (Phase II Randomisation) : BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	29		
Units: L/h				
geometric mean (geometric coefficient of variation)				
Bendamustine (n=32,29)	54.4 (± 60.9)	46.4 (± 93.9)		
Rituximab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: CL of Polatuzumab Vedotin, Bendamustine and Obinutuzumab in Arms E and F

End point title	Phase II: CL of Polatuzumab Vedotin, Bendamustine and Obinutuzumab in Arms E and F[72]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms E and F who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema AUC was not evaluated for polatuzumab and obinutuzumab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[72] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	14		
Units: L/h				
geometric mean (geometric coefficient of variation)				
acMMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Total Ab (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Uncojugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=15,14)	61.3 (± 33.4)	39.9 (± 76.1)		
Obinutuzumab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Arm H (Phase II NF Cohort): CL of Polatuzumab Vedotin (Lyophilized)

End point title	Arm H (Phase II NF Cohort): CL of Polatuzumab Vedotin (Lyophilized)

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. As pre-specified in the protocol the analysis of this endpoint was based on sponsor's discretion however, sponsor opted to not collect data for this endpoint.

End point type	Secondary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4, (cycle length is 21 days for DLBCL cohorts) up to approximately 9 weeks

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	0[73]			
Units: mL/day/kg				
geometric mean (geometric coefficient of variation)	()			

Notes:

[73] - Data was not collected for this endpoint per the sponsor's discretion.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Vss of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1a

End point title	Phase Ib: Vss of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1a[74]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1a (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Overall number analysed' is the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema Vss was not evaluated for bendamustine and rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[74] - 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 only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	6		
Units: mL/kg				
geometric mean (geometric coefficient of variation)				
acMMAE (n=4,6)	73.0 (± 22.3)	82.7 (± 33.2)		
Total Ab (n=4,6)	82.3 (± 9.1)	76.6 (± 25.7)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Rituximab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Vss of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1b

End point title	Phase Ib: Vss of Polatuzumab Vedotin, Bendamustine, and Obinutuzumab in Cohort 1b[75]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Cohort 1b (Phase Ib) who received at least one study treatment and who provided suitable PK samples. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema Vss was not evaluated for bendamustine and obinutuzumab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[75] - 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 only for Phase Ib cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: mL/kg				
arithmetic mean (standard deviation)				
acMMAE (n=5,6)	77.2 (± 38.8)	64.7 (± 23.0)		
Total Ab (n=6,6)	87.5 (± 38.5)	87.9 (± 24.7)		

Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Obinutuzumab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Vss of Polatuzumab Vedotin, Bendamustine and Rituximab in Arms A and C

End point title	Phase II: Vss of Polatuzumab Vedotin, Bendamustine and Rituximab in Arms A and C[76]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms A and C who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema Vss was not evaluated for polatuzumab and rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[76] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	29		
Units: Litres				
geometric mean (geometric coefficient of variation)				
acMMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Total Ab (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=29,29)	36.5 (± 86.4)	34.3 (± 57.7)		
Rituximab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Vss of Bendamustine and Rituximab in Arms B and D

End point title	Phase II: Vss of Bendamustine and Rituximab in Arms B and

End point description:

Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms B and D who received at least one study treatment and who provided suitable PK samples. 'Overall Number Analysed' are the number of participants with data available for analysis. 'Number Analysed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema Vss was not evaluated for rituximab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[77] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm B (Phase II Randomisation) : BR in FL	Arm D (Phase II Randomisation) : BR in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	24		
Units: Litres				
geometric mean (geometric coefficient of variation)				
Bendamustine (n=31,24) Rituximab (n=0,0)	44.9 (± 69.6) 999999 (± 999999)	33.2 (± 62.9) 999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Vss of Polatuzumab Vedotin, Bendamustine and Obinutuzumab in Arms E and F

End point title	Phase II: Vss of Polatuzumab Vedotin, Bendamustine and Obinutuzumab in Arms E and F[78]

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. Here, 999999: participants were not analysed for this PK endpoint at the given timepoint. PK evaluable population included all the ITT participants in Arms E and F who received at least one study treatment and who provided suitable PK samples. Overall number analyzed are the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoints. Due to the sparse sample collection schema Vss was not evaluated for pola and obinutuzumab.

End point type	Secondary

End point timeframe:

Cycle 1 Day 2 (cycle length is 21 days for DLBCL cohorts and 28 days for FL cohorts)

Notes:

[78] - 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 only for Phase II cohorts, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	12		
Units: Litres				
geometric mean (geometric coefficient of variation)				
acMMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Total Ab (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Unconjugated MMAE (n=0,0)	999999 (± 999999)	999999 (± 999999)		
Bendamustine (n=14,12)	51.2 (± 33.6)	31.5 (± 68.1)		
Obinutuzumab (n=0,0)	999999 (± 999999)	999999 (± 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Arm H (Phase II NF Cohort): Vss of Polatuzumab Vedotin (Lyophilized)

End point title	Arm H (Phase II NF Cohort): Vss of Polatuzumab Vedotin (Lyophilized)

End point description:

PK of three pola-related analytes: acMMAE, total antibody, and unconjugated MMAE were measured. As pre-specified in the protocol the analysis of this endpoint was based on sponsor's discretion however, sponsor opted to not collect data for this endpoint.

End point type	Secondary

End point timeframe:

Days 2, 8 and 15 of Cycle 1, Day 1 of Cycle 2 and 4, Day (cycle length is 21 days for DLBCL cohorts) up to approximately 9 weeks

End point values	Arm G (Phase II NF Cohort): Pola+BR in DLBCL			
Subject group type	Subject analysis set			
Number of subjects analysed	0[79]			
Units: milliliters per kilogram (mL/kg)				
geometric mean (geometric coefficient of variation)	()			

Notes:

[79] - Data was not collected for this endpoint per the sponsor's discretion.

Statistical analyses

No statistical analyses for this end point

Secondary: Symptom Severity and Interference According to Therapy-Induced Neuropathy Assessment Score (TINAS) in Arms A-F

End point title	Symptom Severity and Interference According to Therapy-Induced Neuropathy Assessment Score (TINAS) in Arms A-F[80]

End point description:

The TINAS is an 11-item questionnaire that assesses the severity of neuropathy-related symptoms in the last 24 hours. Each item is scored on a 0-10 scale, with 0 being the symptom is not present, and 10 being the symptom is as bad as the participant can imagine. Higher scores indicate more severe disease. ITT population included all randomized participants in Arms A-F (Phase II) irrespective of whether or not they received the study treatment. Here, 'Overall Number Analysed' =number of participants with data available for analysis. 'Number Analysed'=number of participants evaluable for this outcome measure. Here, 99999= SD is not evaluable when only one participant is analysed. 999999= participants were not analysed for this PK endpoint at the given timepoint. Participants from Arm F did not answer a sufficient number of questions at both baseline and end of treatment visit therefore the average score could not be calculated. Scores were averaged at each week.

End point type	Secondary

End point timeframe:

Every week during treatment (up to 24 weeks) and for the first 2 months after treatment, thereafter every month for 10 months or until withdrawal (up to 18 months overall)

Notes:

[80] - 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 only for arms A-F, hence no descriptive statistics were planned for other cohorts for this endpoint.

End point values	Arm A (Phase II Randomisation) : Pola+BR in FL	Arm B (Phase II Randomisation) : BR in FL	Arm C (Phase II Randomisation) : Pola+BR in DLBCL	Arm D (Phase II Randomisation) : BR in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	11	12
Units: Points on scale				
arithmetic mean (standard deviation)				
Baseline (n=15,14,11,12,5,0)	0.2 (± 0.3)	0.5 (± 1.1)	0.4 (± 0.6)	0.6 (± 0.7)
Week 1 (n=2,0,0,01,0)	0.3 (± 0.4)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Week 2 (n=13,13,10,11,3,0)	0.3 (± 0.4)	0.5 (± 1.3)	0.3 (± 0.4)	1.0 (± 1.1)
Week 3 (n=15,13,7,10,4,0)	0.2 (± 0.5)	0.7 (± 1.5)	0.1 (± 0.1)	0.9 (± 0.1)
Week 4 (n=12,13,8,9,5,0)	0.1 (± 0.2)	0.8 (± 1.8)	0.3 (± 0.3)	0.7 (± 0.8)
Week 5 (n=14,13,8,8,4,0)	0.2 (± 0.3)	0.6 (± 1.4)	0.3 (± 0.5)	0.6 (± 0.6)
Week 6 (n=12,13,8,8,4,0)	0.2 (± 0.4)	0.8 (± 1.8)	0.3 (± 0.5)	0.7 (± 1.0)
Week 7 (n=11,11,8,8,4,0)	0.3 (± 0.4)	0.9 (± 1.9)	0.2 (± 0.3)	0.4 (± 0.6)
Week 8 (n=13,12,7,7,4,0)	0.3 (± 0.4)	0.8 (± 1.8)	0.2 (± 0.5)	0.6 (± 0.9)
Week 9 (n=14,14,7,6,5,0)	0.4 (± 0.9)	0.5 (± 0.9)	0.2 (± 0.3)	0.5 (± 0.7)
Week 10 (n=12,13,7,6,3,0)	0.5 (± 0.9)	0.4 (± 0.8)	0.1 (± 0.1)	0.2 (± 0.4)

Week 11 (n=14,13,8,6,5,0)	0.5 (± 1.0)	0.5 (± 0.9)	0.2 (± 0.2)	0.4 (± 0.6)
Week 12 (n=13,12,6,5,3,0)	0.5 (± 1.4)	0.9 (± 2.0)	0.3 (± 0.4)	0.3 (± 0.6)
Week 13 (n=12,14,7,5,4,0)	0.7 (± 1.2)	0.6 (± 1.6)	0.3 (± 0.4)	0.2 (± 0.4)
Week 14 (n=12,11,7,5,5,0)	0.6 (± 1.2)	0.7 (± 1.8)	0.3 (± 0.3)	0.4 (± 0.6)
Week 15 (n=11,12,7,5,3,0)	0.2 (± 0.3)	0.7 (± 1.7)	0.4 (± 0.5)	0.4 (± 0.4)
Week 16 (n=11,11,5,5,5,0)	0.4 (± 0.5)	0.8 (± 1.8)	0.4 (± 0.4)	0.4 (± 0.5)
Week 17 (n=11,11,6,5,4,0)	0.2 (± 0.3)	0.8 (± 1.8)	0.5 (± 0.7)	0.4 (± 0.6)
Week 18 (n=10,11,6,2,4,0)	0.2 (± 0.3)	0.7 (± 1.8)	0.3 (± 0.4)	0.1 (± 0.1)
Week 19 (n=12,9,6,4,4,0)	0.2 (± 0.3)	0.8 (± 2.0)	0.4 (± 0.7)	0.5 (± 0.8)
Week 20 (n=11,9,5,3,4,0)	0.0 (± 0.2)	0.8 (± 1.9)	0.6 (± 0.8)	0.1 (± 0.1)
Week 21 (n=7,10,5,3,4,0)	0.3 (± 0.3)	0.9 (± 1.9)	0.5 (± 0.5)	0.1 (± 0.1)
Week 22 (n=9,9,3,1,3,0)	0.2 (± 0.2)	0.8 (± 2.0)	0.9 (± 1.5)	0.0 (± 99999)
Week 23 (n=7,9,7,1,3,0)	0.2 (± 0.3)	0.8 (± 2.2)	0.6 (± 0.7)	0.0 (± 99999)
Week 24 (n=7,8,7,2,4,0)	0.4 (± 0.6)	1.0 (± 2.3)	0.5 (± 0.7)	0.0 (± 0.1)
Week 25 (n=8,7,6,1,2,0)	0.2 (± 0.2)	0.2 (± 0.2)	0.3 (± 0.4)	0.0 (± 99999)
Week 26 (n=7,7,6,2,3,0)	0.6 (± 0.8)	3.3 (± 4.4)	0.4 (± 0.6)	0.0 (± 99999)
Week 27 (n=5,2,7,1,0,0)	0.3 (± 0.3)	1.1 (± 2.5)	0.5 (± 0.6)	0.1 (± 0.1)
Week 28 (n=8,6,7,1,2,0)	0.5 (± 0.6)	1.2 (± 2.6)	0.5 (± 0.7)	0.0 (± 99999)
Week 29 (n=8,7,7,1,3,0)	0.2 (± 0.2)	0.8 (± 2.1)	0.7 (± 0.7)	0.0 (± 99999)
Week 30 (n=6,8,4,1,2,0)	0.7 (± 1.1)	0.7 (± 1.9)	0.8 (± 0.8)	0.0 (± 99999)
Week 31 (n=7,4,3,1,3,0)	0.3 (± 0.3)	0.0 (± 0.1)	1.3 (± 0.9)	0.0 (± 99999)
Week 32 (n=5,6,4,0,2,0)	0.4 (± 0.4)	0.1 (± 0.1)	1.0 (± 0.9)	999999 (± 999999)
Week 33 (n=4,6,4,0,3,0)	0.3 (± 0.3)	0.1 (± 0.2)	1.0 (± 1.0)	999999 (± 999999)
Week 34 (n=6,4,3,0,2,0)	0.2 (± 0.2)	1.3 (± 2.4)	0.8 (± 0.5)	999999 (± 999999)
Week 35 (n=4,1,3,2,1,0)	0.3 (± 0.3)	0.0 (± 99999)	1.2 (± 0.7)	0.6 (± 0.9)
Week 36 (n=3,2,3,0,2,0)	0.5 (± 0.3)	0.2 (± 0.3)	1.2 (± 0.6)	999999 (± 999999)
Week 37 (n=3,5,4,0,2,0)	0.4 (± 0.4)	0.1 (± 0.1)	1.1 (± 0.8)	999999 (± 999999)
Week 38 (n=3,1,2,0,1,0)	0.4 (± 0.4)	0.1 (± 99999)	1.5 (± 0.4)	999999 (± 999999)
Week 39 (n=5,1,2,1,1,0)	0.7 (± 0.9)	0.0 (± 99999)	1.5 (± 0.5)	0.0 (± 99999)
Week 40 (n=3,1,3,0,2,0)	0.5 (± 0.4)	0.0 (± 99999)	0.9 (± 0.4)	999999 (± 999999)
Week 41 (n=2,7,4,0,2,0)	0.6 (± 0.6)	0.7 (± 1.6)	1.4 (± 1.2)	999999 (± 999999)
Week 42 (n=3,1,1,0,1,0)	0.5 (± 0.5)	0.0 (± 99999)	0.3 (± 99999)	9999 (± 9999)
Week 43 (n=4,1,1,1,0)	0.3 (± 0.4)	0.0 (± 99999)	0.6 (± 99999)	0.0 (± 99999)
Week 44 (n=1,1,2,0,1,0)	1.6 (± 99999)	0.0 (± 99999)	0.2 (± 0.3)	999999 (± 999999)
Week 45 (n=3,7,2,0,2,0)	0.8 (± 0.7)	0.1 (± 0.2)	1.0 (± 1.2)	999999 (± 999999)
Week 46 (n=2,1,1,0,1,0)	1.1 (± 0.7)	0.1 (± 99999)	0.2 (± 99999)	999999 (± 999999)
Week 47 (n=4,1,1,0,1,0)	0.4 (± 0.6)	0.0 (± 99999)	0.1 (± 99999)	999999 (± 999999)
Week 48 (n=0,2,3,0,1,0)	999999 (± 9999999999)	0.8 (± 0.9)	0.2 (± 0.2)	999999 (± 999999)
Week 49 (n=2,7,2,0,2,0)	0.6 (± 0.6)	0.0 (± 0.0)	1.1 (± 1.4)	999999 (± 999999999)
Week 50 (n=2,1,1,0,1,0)	1.0 (± 0.2)	0.1 (± 99999)	0.2 (± 99999)	999999 (± 999999)
Week 51 (n=2,1,1,0,1,0)	0.1 (± 0.2)	0.0 (± 99999)	0.2 (± 99999)	999999 (± 999999)

Week 52 (n=1,2,1,0,1,0)	0.4 (± 99999)	0.4 (± 0.5)	0.2 (± 99999)	999999 (± 999999)
Week 53 (n=1,5,1,0,2,0)	0.2 (± 99999)	0.7 (± 1.5)	0.2 (± 99999)	999999 (± 999999)
Week 54 (n=2,1,1,0,1,0)	0.8 (± 0.6)	0.0 (± 99999)	0.2 (± 99999)	999999 (± 999999)
Week 55 (n=2,1,1,0,1,0)	0.3 (± 0.5)	0.2 (± 99999)	0.2 (± 99999)	999999 (± 999999)
Week 56 (n=2,1,2,0,0,0)	0.6 (± 0.3)	0.2 (± 99999)	0.0 (± 0.1)	999999 (± 999999)
Week 57 (n=1,6,2,0,2,0)	0.3 (± 99999)	0.0 (± 0.0)	1.5 (± 2.1)	999999 (± 999999)
Week 58 (n=4,0,1,0,1,0)	0.7 (± 0.6)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 59 (n=2,1,1,0,1,0)	0.0 (± 0.1)	0.0 (± 99999)	0.0 (± 99999)	999999 (± 999999)
Week 60 (n=1,0,1,0,0,0)	0.4 (± 99999)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 61 (n=3,6,2,0,2,0)	0.4 (± 0.3)	0.3 (± 0.5)	1.5 (± 2.1)	999999 (± 999999)
Week 62 (n=2,0,1,0,1,0)	0.7 (± 1.0)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 63 (n=3,1,1,0,1,0)	0.4 (± 0.7)	0.0 (± 99999)	0.0 (± 99999)	999999 (± 999999)
Week 64 (n=1,1,2,0,1,0)	0.4 (± 99999)	1.1 (± 99999)	0.1 (± 0.2)	999999 (± 999999)
Week 65 (n=2,4,3,0,1,0)	0.2 (± 0.0)	0.0 (± 0.0)	0.8 (± 1.3)	999999 (± 999999)
Week 66 (n=3,0,1,0,1,0)	0.6 (± 0.7)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 67 (n=2,0,1,0,1,0)	0.2 (± 0.3)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 68 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 69 (n=1,5,2,0,1,0)	0.2 (± 99999)	0.3 (± 0.5)	1.5 (± 2.1)	999999 (± 999999)
Week 70 (n=2,0,1,0,1,0)	0.7 (± 1.0)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 71 (n=2,0,1,0,1,0)	0.1 (± 0.1)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 72 (n=0,1,1,01,0)	999999 (± 999999)	1.2 (± 99999)	0.0 (± 99999)	999999 (± 999999)
Week 73 (n=2,3,2,0,1,0)	0.4 (± 0.3)	0.0 (± 0.0)	1.3 (± 1.8)	999999 (± 999999)
Week 74 (n=3,0,1,0,1,0)	1.3 (± 0.7)	999999 (± 999999)	0.0 (± 99999)	999999 (± 9999999999)
Week 75 (n=2,0,1,0,1,0)	0.2 (± 0.0)	999999 (± 999999)	0.0 (± 99999)	9999 (± 9999)
Week 76 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.7 (± 99999)	999999 (± 999999)
Week 77 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	1.5 (± 99999)	9999 (± 9999)
Week 78 (n=1,0,1,0,0,0)	0.7 (± 99999)	999999 (± 999999)	1.4 (± 99999)	999999 (± 999999)
Week 79 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	1.4 (± 99999)	9999 (± 9999)
Week 80 (n=1,0,1,01,0)	0.0 (± 99999)	999999 (± 999999)	1.1 (± 99999)	999999 (± 999999)
Week 81 (n=0,0,1,0,0,0)	999999 (± 999999)	999999 (± 999999)	0.6 (± 99999)	999999 (± 999999)
Week 82 (n=0,0,1,0,0,0)	9999999999 (± 999999)	999999 (± 999999)	0.6 (± 99999)	999999 (± 999999)

Week 83 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.6 (± 99999)	999999 (± 999999)
Week 84 (n=1,0,1,0,0,0)	0.0 (± 99999)	999999 (± 999999)	0.6 (± 99999)	999999 (± 999999)
Week 85 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.6 (± 99999)	999999 (± 999999)
Week 86 (n=1,0,1,0,1,0)	0.6 (± 99999)	999999 (± 999999)	0.6 (± 99999)	999999 (± 999999)
Week 89 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.0 (± 999999)	999999 (± 999999)
Week 90 (n=0,0,0,0,1,0)	0.7 (± 99999)	999999 (± 999999)	0.5 (± 999999)	999999 (± 9999)
Week 91 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 9999)	0.0 (± 999999)	999999 (± 9999)
Week 92 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.0 (± 999999)	999999 (± 999999)
Week 93 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.1 (± 999999)	999999 (± 999999)
Week 94 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 95 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.5 (± 99999)	999999 (± 999999)
Week 96 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 97 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.2 (± 999999)	999999 (± 999999)
Week 98 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.0 (± 99999)	999999 (± 999999)
Week 99 (n=0,0,1,0,1,0)	0.6 (± 1.8)	0.6 (± 1.8)	0.1 (± 99999)	0.8 (± 1.0)
Week 100 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.3 (± 99999)	999999 (± 999999)
Week 101 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Week 102 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.2 (± 99999)	999999 (± 999999)
Week 103 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.3 (± 99999)	999999 (± 999999)
Week 104 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.2 (± 99999)	999999 (± 999999)
Week 105 (n=0,0,1,0,1,0)	999999 (± 999999)	999999 (± 999999)	0.1 (± 99999)	999999 (± 999999)
Week 107 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Week 108 (n=0,0,0,0,1,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
End of Treatment (n=15,14,11,12,5,0)	0.4 (± 0.6)	0.6 (± 1.8)	0.5 (± 0.8)	0.8 (± 1.0)

End point values	Arm E (Phase II Expansion): Pola+BG in FL	Arm F (Phase II Expansion): Pola+BG in DLBCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	0[81]		
Units: Points on scale				
arithmetic mean (standard deviation)				
Baseline (n=15,14,11,12,5,0)	0.8 (± 1.6)	()		
Week 1 (n=2,0,0,01,0)	0.0 (± 99999)	()		

Week 2 (n=13,13,10,11,3,0)	0.2 (± 0.2)	()		
Week 3 (n=15,13,7,10,4,0)	0.0 (± 0.1)	()		
Week 4 (n=12,13,8,9,5,0)	0.2 (± 0.4)	()		
Week 5 (n=14,13,8,8,4,0)	0.1 (± 0.2)	()		
Week 6 (n=12,13,8,8,4,0)	0.1 (± 0.3)	()		
Week 7 (n=11,11,8,8,4,0)	0.0 (± 0.1)	()		
Week 8 (n=13,12,7,7,4,0)	0.2 (± 0.4)	()		
Week 9 (n=14,14,7,6,5,0)	0.1 (± 0.3)	()		
Week 10 (n=12,13,7,6,3,0)	0.1 (± 0.2)	()		
Week 11 (n=14,13,8,6,5,0)	0.1 (± 0.1)	()		
Week 12 (n=13,12,6,5,3,0)	0.2 (± 0.2)	()		
Week 13 (n=12,14,7,5,4,0)	0.3 (± 0.4)	()		
Week 14 (n=12,11,7,5,5,0)	0.2 (± 0.4)	()		
Week 15 (n=11,12,7,5,3,0)	0.9 (± 1.6)	()		
Week 16 (n=11,11,5,5,5,0)	0.3 (± 0.7)	()		
Week 17 (n=11,11,6,5,4,0)	0.3 (± 0.5)	()		
Week 18 (n=10,11,6,2,4,0)	0.3 (± 0.5)	()		
Week 19 (n=12,9,6,4,4,0)	0.3 (± 0.5)	()		
Week 20 (n=11,9,5,3,4,0)	0.3 (± 0.4)	()		
Week 21 (n=7,10,5,3,4,0)	0.3 (± 0.3)	()		
Week 22 (n=9,9,3,1,3,0)	0.5 (± 0.6)	()		
Week 23 (n=7,9,7,1,3,0)	0.5 (± 0.6)	()		
Week 24 (n=7,8,7,2,4,0)	0.3 (± 0.3)	()		
Week 25 (n=8,7,6,1,2,0)	0.1 (± 0.1)	()		
Week 26 (n=7,7,6,2,3,0)	999999 (± 999999)	()		
Week 27 (n=5,2,7,1,0,0)	0.4 (± 0.4)	()		
Week 28 (n=8,6,7,1,2,0)	0.1 (± 0.2)	()		
Week 29 (n=8,7,7,1,3,0)	0.1 (± 0.2)	()		
Week 30 (n=6,8,4,1,2,0)	0.1 (± 0.1)	()		
Week 31 (n=7,4,3,1,3,0)	0.1 (± 0.1)	()		
Week 32 (n=5,6,4,0,2,0)	0.2 (± 0.3)	()		
Week 33 (n=4,6,4,0,3,0)	0.2 (± 0.2)	()		
Week 34 (n=6,4,3,0,2,0)	0.2 (± 0.3)	()		
Week 35 (n=4,1,3,2,1,0)	0.4 (± 99999)	()		
Week 36 (n=3,2,3,0,2,0)	0.1 (± 0.2)	()		
Week 37 (n=3,5,4,0,2,0)	0.2 (± 0.3)	()		
Week 38 (n=3,1,2,0,1,0)	0.3 (± 99999)	()		
Week 39 (n=5,1,2,1,1,0)	0.3 (± 99999)	()		
Week 40 (n=3,1,3,0,2,0)	0.1 (± 0.2)	()		
Week 41 (n=2,7,4,0,2,0)	0.3 (± 0.4)	()		
Week 42 (n=3,1,1,0,1,0)	0.5 (± 99999)	()		
Week 43 (n=4,1,1,1,0)	0.4 (± 99999)	()		
Week 44 (n=1,1,2,0,1,0)	0.7 (± 99999)	()		
Week 45 (n=3,7,2,0,2,0)	0.3 (± 0.4)	()		
Week 46 (n=2,1,1,0,1,0)	0.5 (± 99999)	()		
Week 47 (n=4,1,1,0,1,0)	0.8 (± 999999)	()		
Week 48 (n=0,2,3,0,1,0)	0.6 (± 99999)	()		
Week 49 (n=2,7,2,0,2,0)	0.3 (± 0.4)	()		
Week 50 (n=2,1,1,0,1,0)	0.5 (± 99999)	()		
Week 51 (n=2,1,1,0,1,0)	0.5 (± 99999)	()		
Week 52 (n=1,2,1,0,1,0)	0.5 (± 99999)	()		

Week 53 (n=1,5,1,0,2,0)	0.2 (± 0.3)	()		
Week 54 (n=2,1,1,0,1,0)	0.5 (± 99999)	()		
Week 55 (n=2,1,1,0,1,0)	0.5 (± 99999)	()		
Week 56 (n=2,1,2,0,0,0)	999999 (± 999999)	()		
Week 57 (n=1,6,2,0,2,0)	0.2 (± 0.3)	()		
Week 58 (n=4,0,1,0,1,0)	0.6 (± 99999)	()		
Week 59 (n=2,1,1,0,1,0)	0.6 (± 99999)	()		
Week 60 (n=1,0,1,0,0,0)	999999 (± 999999)	()		
Week 61 (n=3,6,2,0,2,0)	0.3 (± 0.5)	()		
Week 62 (n=2,0,1,0,1,0)	0.6 (± 99999)	()		
Week 63 (n=3,1,1,0,1,0)	0.8 (± 99999)	()		
Week 64 (n=1,1,2,0,1,0)	0.7 (± 99999)	()		
Week 65 (n=2,4,3,0,1,0)	0.0 (± 99999)	()		
Week 66 (n=3,0,1,0,1,0)	0.8 (± 99999)	()		
Week 67 (n=2,0,1,0,1,0)	0.9 (± 99999)	()		
Week 68 (n=0,0,1,0,1,0)	1.2 (± 99999)	()		
Week 69 (n=1,5,2,0,1,0)	0.0 (± 99999)	()		
Week 70 (n=2,0,1,0,1,0)	1.0 (± 99999)	()		
Week 71 (n=2,0,1,0,1,0)	0.8 (± 99999)	()		
Week 72 (n=0,1,1,01,0)	0.9 (± 99999)	()		
Week 73 (n=2,3,2,0,1,0)	0.0 (± 99999)	()		
Week 74 (n=3,0,1,0,1,0)	0.8 (± 99999)	()		
Week 75 (n=2,0,1,0,1,0)	1.1 (± 99999)	()		
Week 76 (n=0,0,1,0,1,0)	0.6 (± 99999)	()		
Week 77 (n=0,0,1,0,1,0)	0.9 (± 99999)	()		
Week 78 (n=1,0,1,0,0,0)	999999 (± 999999)	()		
Week 79 (n=0,0,1,0,1,0)	0.8 (± 99999)	()		
Week 80 (n=1,0,1,01,0)	0.8 (± 99999)	()		
Week 81 (n=0,0,1,0,0,0)	999999 (± 999999)	()		
Week 82 (n=0,0,1,0,0,0)	999999 (± 999999)	()		
Week 83 (n=0,0,1,0,1,0)	0.8 (± 99999)	()		
Week 84 (n=1,0,1,0,0,0)	999999 (± 999999)	()		
Week 85 (n=0,0,1,0,1,0)	0.6 (± 99999)	()		
Week 86 (n=1,0,1,0,1,0)	0.6 (± 99999)	()		
Week 89 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 90 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 91 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 92 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 93 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 94 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		
Week 95 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		
Week 96 (n=0,0,1,0,1,0)	0.8 (± 99999)	()		
Week 97 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 98 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		
Week 99 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		
Week 100 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		
Week 101 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 102 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		

Week 103 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		
Week 104 (n=0,0,1,0,1,0)	0.7 (± 99999)	()		
Week 105 (n=0,0,1,0,1,0)	0.8 (± 99999)	()		
Week 107 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
Week 108 (n=0,0,0,0,1,0)	0.7 (± 99999)	()		
End of Treatment (n=15,14,11,12,5,0)	0.1 (± 0.2)	()		

Notes:

[81] - No participants were analysed from this Arm.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From the study start up to the end of the study (up to approximately 84 months)

Adverse event reporting additional description:

Serious and non-serious adverse events were reported for safety population. Safety population=participants who received at least one dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine, 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm A (Phase II Randomization): Pola+BR in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Arm B (Phase II Randomization): BR in FL

Reporting group description:

Participants with FL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 28 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Reporting group title	Arm C (Phase II Randomization): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Reporting group title	Arm D (Phase II Randomization): BR in DLBCL

Reporting group description:

Participants with DLBCL received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1 (each cycle is 21 days), thereafter on Days 1 and 2 of Cycles 2 to 6 in combination with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6.

Reporting group title	Arm E (Phase II Expansion): Pola+BG in FL

Reporting group description:

Participants with FL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 28 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm F (Phase II Expansion): Pola+BG in DLBCL

Reporting group description:

Participants with DLBCL received pola, 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and obinutuzumab 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 in combination with pola.

Reporting group title	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL

Reporting group description:

Participants with DLBCL received pola (lyophilized formulation), 1.8 mg/kg, as IV infusion on Day 2 of Cycle 1 (each cycle is 21 days), and thereafter on Day 1 of Cycles 2 to 6. Participants also received bendamustine 90 mg/m^2, as IV infusion on Days 2 and 3 of Cycle 1, and thereafter on Days 1 and 2 of Cycles 2 to 6 and rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1 to 6, in combination with pola.

Serious adverse events	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	4 / 6 (66.67%)	2 / 6 (33.33%)
number of deaths (all causes)	2	2	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ADENOCARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCYTIC LEUKAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 MELANOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (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
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPIGLOTTIC CANCER			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC CARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISTRIBUTIVE SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			

ASTHENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (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
SUDDEN DEATH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE PULMONARY OEDEMA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOPNEUMOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVENTILATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MORAXELLA TEST POSITIVE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT DECREASED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEAD INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL FEVER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FLUTTER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC ARREST			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CARDIOMYOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
CAROTID ARTERY OCCLUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGE INTRACRANIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROCEPHALUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOENCEPHALOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH ULCERATION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTION GASTRIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
HEPATIC CIRRHOSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC HEPATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
DRUG ERUPTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL TOXOPLASMOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIAL SEPSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (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
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 CHORIORETINITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOMEGALOVIRUS COLITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 ENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 BACTERIAL INFECTION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GIARDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS E			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HUMAN ANAPLASMOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED LYMPHOCELE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 INTESTINE INFECTION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENINGOENCEPHALITIS HERPETIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARONYCHIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (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
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 CYTOMEGALOVIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 FUNGAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 PNEUMOCOCCAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (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
SEPTIC SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISSEMINATED VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 ACCESS SITE CELLULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
HYPOKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL	Arm A (Phase II Randomization): Pola+BR in FL	Arm B (Phase II Randomization): BR in FL
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	25 / 38 (65.79%)	12 / 41 (29.27%)
number of deaths (all causes)	4	16	11
number of deaths resulting from adverse events	1	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ADENOCARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCYTIC LEUKAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 MELANOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
PROSTATE CANCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPIGLOTTIC CANCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC CARCINOMA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL CANCER			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISTRIBUTIVE SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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

DEATH			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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	1 / 6 (16.67%)	2 / 38 (5.26%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
Respiratory, thoracic and mediastinal disorders			
ACUTE PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOPNEUMOPATHY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
HAEMOPTYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVENTILATION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
HYPOXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
PULMONARY EMBOLISM			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
Investigations			
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MORAXELLA TEST POSITIVE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
FALL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEAD INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL FEVER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 FLUTTER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC ARREST			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
CARDIAC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
CARDIOMYOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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

MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 THROMBOSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CAROTID ARTERY OCCLUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
CEREBROVASCULAR ACCIDENT			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
HAEMORRHAGE INTRACRANIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROCEPHALUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOENCEPHALOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			

subjects affected / exposed	1 / 6 (16.67%)	6 / 38 (15.79%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	7 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (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
PANCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
CONSTIPATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	3 / 38 (7.89%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
MOUTH ULCERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			

subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
OBSTRUCTION GASTRIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
Hepatobiliary disorders			
HEPATIC CIRRHOSIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC HEPATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
DRUG ERUPTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH ERYTHEMATOUS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
HYDRONEPHROSIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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			
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL TOXOPLASMOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIAL SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
CYTOMEGALOVIRUS CHORIORETINITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOMEGALOVIRUS COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 ENTERITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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 VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL BACTERIAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GIARDIASIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS E			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HUMAN ANAPLASMOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED LYMPHOCELE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 INTESTINE INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
LOWER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENINGOENCEPHALITIS HERPETIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
PARONYCHIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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	2 / 6 (33.33%)	7 / 38 (18.42%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 2	3 / 8	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 CYTOMEGALOVIRAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 FUNGAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 PNEUMOCOCCAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 VIRAL			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (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
POST PROCEDURAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 SYNCYTIAL VIRUS INFECTION			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SEPTIC SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
DISSEMINATED VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 ACCESS SITE CELLULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
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 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (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
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm C (Phase II Randomization): Pola+BR in DLBCL	Arm D (Phase II Randomization): BR in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL
Total subjects affected by serious adverse events			
subjects affected / exposed	27 / 39 (69.23%)	24 / 39 (61.54%)	8 / 20 (40.00%)
number of deaths (all causes)	26	30	3
number of deaths resulting from adverse events	3	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ADENOCARCINOMA			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCYTIC LEUKAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 MELANOMA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
EPIGLOTTIC CANCER			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
PANCREATIC CARCINOMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 CANCER			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
DISTRIBUTIVE SHOCK			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
HYPOTENSION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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			
ASTHENIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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

GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
PYREXIA			
subjects affected / exposed	5 / 39 (12.82%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	2 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE PULMONARY OEDEMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
BRONCHOPNEUMOPATHY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
HYPERVENTILATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (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
PNEUMOTHORAX			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 OEDEMA			

subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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			
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MORAXELLA TEST POSITIVE			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
WEIGHT DECREASED			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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			
FALL			

subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
HEAD INJURY			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
POST PROCEDURAL FEVER			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
ATRIAL FLUTTER			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
CARDIAC ARREST			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
CARDIOMYOPATHY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
TACHYCARDIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
ATRIAL THROMBOSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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			
CAROTID ARTERY OCCLUSION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			

subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
HAEMORRHAGE INTRACRANIAL			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
HYDROCEPHALUS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOENCEPHALOPATHY			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
SEIZURE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOCAL CORD PARALYSIS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
BRAIN OEDEMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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	2 / 39 (5.13%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			

subjects affected / exposed	4 / 39 (10.26%)	4 / 39 (10.26%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	3 / 4	2 / 4	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOPENIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCYTOPENIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
THROMBOCYTOPENIA			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (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
ASCITES			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER HAEMORRHAGE			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	0 / 20 (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
ENTERITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH ULCERATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTION GASTRIC			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
PANCREATITIS			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
ENTEROCOLITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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			
HEPATIC CIRRHOSIS			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC HEPATITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
DRUG ERUPTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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	1 / 39 (2.56%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			

subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
RENAL FAILURE			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
FLANK PAIN			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACTERAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL TOXOPLASMOSIS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
CLOSTRIDIAL SEPSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 CHORIORETINITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOMEGALOVIRUS COLITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 ENTERITIS			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
DIVERTICULITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS VIRAL			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 BACTERIAL INFECTION			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
GIARDIASIS			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS E			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 VIRUS INFECTION			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
HERPES ZOSTER			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HUMAN ANAPLASMOSIS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
INFECTED LYMPHOCELE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
LARGE INTESTINE INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
MENINGOENCEPHALITIS HERPETIC			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
OESOPHAGEAL CANDIDIASIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORAL INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARONYCHIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION BACTERIAL			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
PNEUMONIA			

subjects affected / exposed	4 / 39 (10.26%)	4 / 39 (10.26%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	2 / 5	0 / 4	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 1	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 CYTOMEGALOVIRAL			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
PNEUMONIA FUNGAL			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 PNEUMOCOCCAL			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
PNEUMONIA VIRAL			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (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
PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
RESPIRATORY SYNCYTIAL VIRUS INFECTION			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHINOVIRUS INFECTION			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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	2 / 39 (5.13%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			

subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISSEMINATED VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
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 ACCESS SITE CELLULITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (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
DEHYDRATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 20 (65.00%)	57 / 106 (53.77%)	
number of deaths (all causes)	18	65	
number of deaths resulting from adverse events	0	4	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL ADENOCARCINOMA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOCYTIC LEUKAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT MELANOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATE CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPIGLOTTIC CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATIC CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CANCER			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DISTRIBUTIVE SHOCK			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
subjects affected / exposed	1 / 20 (5.00%)	3 / 106 (2.83%)	
occurrences causally related to treatment / all	0 / 1	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEATH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
subjects affected / exposed	2 / 20 (10.00%)	7 / 106 (6.60%)	
occurrences causally related to treatment / all	0 / 3	3 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUDDEN DEATH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE PULMONARY OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHOPNEUMOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			

subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOPTYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERVENTILATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOTHORAX			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY OEDEMA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MORAXELLA TEST POSITIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WEIGHT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
FALL			

subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEAD INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL FEVER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FLUTTER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ARREST			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIOMYOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL ISCHAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
CAROTID ARTERY OCCLUSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBROVASCULAR ACCIDENT			

subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGE INTRACRANIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDROCEPHALUS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
LEUKOENCEPHALOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEIZURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRAIN OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEBRILE NEUTROPENIA			

subjects affected / exposed	2 / 20 (10.00%)	9 / 106 (8.49%)	
occurrences causally related to treatment / all	2 / 2	3 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEUKOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCYTOPENIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASCITES			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONSTIPATION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENAL ULCER HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTERITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MOUTH ULCERATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			

subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OBSTRUCTION GASTRIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOLITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
HEPATIC CIRRHOSIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC HEPATITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
DRUG ERUPTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDRONEPHROSIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLANK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL TOXOPLASMOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIAL SEPSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOMEGALOVIRUS CHORIORETINITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOMEGALOVIRUS COLITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOMEGALOVIRUS ENTERITIS			

subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOLITIS VIRAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL BACTERIAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GIARDIASIS			

subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATITIS E			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HUMAN ANAPLASMOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTED LYMPHOCELE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENINGOENCEPHALITIS HERPETIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
OESOPHAGEAL CANDIDIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARONYCHIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL INFECTION BACTERIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			

subjects affected / exposed	0 / 20 (0.00%)	6 / 106 (5.66%)	
occurrences causally related to treatment / all	0 / 0	5 / 6	
deaths causally related to treatment / all	0 / 0	1 / 1	
PNEUMONIA BACTERIAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA CYTOMEGALOVIRAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA FUNGAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
PNEUMONIA PNEUMOCOCCAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA VIRAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY SYNCYTIAL VIRUS INFECTION			

subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	1 / 20 (5.00%)	7 / 106 (6.60%)	
occurrences causally related to treatment / all	0 / 1	7 / 9	
deaths causally related to treatment / all	0 / 1	2 / 2	
SEPTIC SHOCK			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROSEPSIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DISSEMINATED VARICELLA ZOSTER VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR ACCESS SITE CELLULITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEHYDRATION			
subjects affected / exposed	1 / 20 (5.00%)	3 / 106 (2.83%)	
occurrences causally related to treatment / all	1 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR LYSIS SYNDROME			

subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in DLBCL	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in FL	Cohort 1a (Phase Ib Safety Run-In): Pola+BR in FL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
HODGKIN'S DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	3	0
HYPOTENSION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
HYPERTENSION			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PALLOR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
CHILLS			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	1 / 6 (16.67%)
occurrences (all)	4	5	2
DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	4 / 6 (66.67%)	3 / 6 (50.00%)	4 / 6 (66.67%)
occurrences (all)	5	3	4
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
OEDEMA PERIPHERAL			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	4	4	1
PAIN			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
CATHETER SITE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
CATHETER SITE PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
EARLY SATIETY			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
GAIT DISTURBANCE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Immune system disorders			
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TESTICULAR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TESTICULAR SWELLING			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	1 / 6 (16.67%)
occurrences (all)	1	6	1
DYSPHONIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
DYSPNOEA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	2	3
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
HYPOXIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
NASAL CONGESTION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
OROPHARYNGEAL PAIN			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	2	3	0
RHINORRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
THROAT IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BRONCHOSPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NASAL DISCHARGE DISCOLOURATION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
ORGANISING PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

PULMONARY EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
SINUS PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TACHYPNOEA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	3 / 6 (50.00%)
occurrences (all)	1	1	3
CONFUSIONAL STATE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DELIRIUM			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
IRRITABILITY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SUICIDAL IDEATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMOGLOBIN DECREASED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
WEIGHT DECREASED			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	2
WEIGHT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
AMYLASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
LIMB INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
COMMINUTED FRACTURE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WOUND			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
TACHYCARDIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
BUNDLE BRANCH BLOCK RIGHT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
DYSGEUSIA			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
HEADACHE			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
HYPOAESTHESIA			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
PARAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
POST HERPETIC NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
AMNESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSKINESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERONEAL NERVE PALSY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
POLYNEUROPATHY			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
TREMOR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
LEUKOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	8	4
PANCYTOPENIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0

THROMBOCYTOPENIA			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	2
COAGULOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMOLYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
IMMUNE THROMBOCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
HYPOACUSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
EYE DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
EYE PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
GLAUCOMA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	1 / 6 (16.67%)	4 / 6 (66.67%)	3 / 6 (50.00%)
occurrences (all)	1	7	3
DIARRHOEA			
subjects affected / exposed	2 / 6 (33.33%)	4 / 6 (66.67%)	2 / 6 (33.33%)
occurrences (all)	5	7	8
DRY MOUTH			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
DYSPEPSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

FLATULENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
NAUSEA			
subjects affected / exposed	3 / 6 (50.00%)	5 / 6 (83.33%)	3 / 6 (50.00%)
occurrences (all)	4	7	4
ODYNOPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
VOMITING			
subjects affected / exposed	1 / 6 (16.67%)	5 / 6 (83.33%)	2 / 6 (33.33%)
occurrences (all)	2	6	3
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ANAL SPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DEFAECATION URGENCY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
GINGIVAL DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GINGIVAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMATEMESIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LIP DRY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
NONINFECTIVE GINGIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
RECTAL DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			

ALOPECIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 6 (50.00%)	3 / 6 (50.00%)
occurrences (all)	0	3	3
DRY SKIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
NIGHT SWEATS			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	1	1	2
PRURITUS			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
RASH			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	3
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
DERMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SKIN DISCOLOURATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ANURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
BONE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
MUSCULAR WEAKNESS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
MYALGIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CERVICAL SPINAL STENOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC DEGENERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PNEUMONIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
CYSTITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS VIRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
SKIN INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS SITE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	2	2	3
DEHYDRATION			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
HYPERURICAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HYPOCALCAEMIA			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
HYPOKALAEMIA			
subjects affected / exposed	3 / 6 (50.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	3	4	2
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	5

HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
HYPERPHOSPHATAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
LACTIC ACIDOSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
MALNUTRITION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Non-serious adverse events	Cohort 1b (Phase Ib Safety Run-In): Pola+BG in DLBCL	Arm A (Phase II Randomization): Pola+BR in FL	Arm B (Phase II Randomization): BR in FL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	38 / 38 (100.00%)	39 / 41 (95.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
HODGKIN'S DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ENDOMETRIAL ADENOCARCINOMA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	1 / 41 (2.44%)
occurrences (all)	0	2	1
HYPERTENSION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	0	2	3
EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	2
PALLOR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	1 / 6 (16.67%)	7 / 38 (18.42%)	3 / 41 (7.32%)
occurrences (all)	1	9	5
CHILLS			
subjects affected / exposed	2 / 6 (33.33%)	0 / 38 (0.00%)	3 / 41 (7.32%)
occurrences (all)	3	0	3
DISCOMFORT			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	2 / 6 (33.33%)	16 / 38 (42.11%)	13 / 41 (31.71%)
occurrences (all)	2	20	22
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	4 / 41 (9.76%)
occurrences (all)	0	5	4
PYREXIA			
subjects affected / exposed	2 / 6 (33.33%)	8 / 38 (21.05%)	4 / 41 (9.76%)
occurrences (all)	2	11	5
PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
EARLY SATIETY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			

subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
TESTICULAR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
TESTICULAR SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	0 / 6 (0.00%)	6 / 38 (15.79%)	3 / 41 (7.32%)
occurrences (all)	0	7	3
DYSPHONIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
DYSPNOEA			

subjects affected / exposed	2 / 6 (33.33%)	4 / 38 (10.53%)	4 / 41 (9.76%)
occurrences (all)	3	4	4
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
HYPOXIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	0	2	2
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	4 / 38 (10.53%)	2 / 41 (4.88%)
occurrences (all)	0	5	3
PLEURAL EFFUSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
RHINORRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
THROAT IRRITATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
BRONCHOSPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HICCUPS			

subjects affected / exposed	1 / 6 (16.67%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
NASAL DISCHARGE DISCOLOURATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ORGANISING PNEUMONIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
SINUS CONGESTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
SINUS PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
TACHYPNOEA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	1 / 6 (16.67%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	1	3	2
DEPRESSION			

subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	2 / 41 (4.88%)
occurrences (all)	0	3	2
INSOMNIA			
subjects affected / exposed	1 / 6 (16.67%)	3 / 38 (7.89%)	3 / 41 (7.32%)
occurrences (all)	1	3	3
CONFUSIONAL STATE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DELIRIUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
IRRITABILITY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SUICIDAL IDEATION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
BLOOD CREATININE INCREASED			

subjects affected / exposed	1 / 6 (16.67%)	3 / 38 (7.89%)	2 / 41 (4.88%)
occurrences (all)	1	6	2
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	1 / 41 (2.44%)
occurrences (all)	0	2	2
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	2	1
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	10	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	2 / 41 (4.88%)
occurrences (all)	0	15	2
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	0 / 41 (0.00%)
occurrences (all)	0	18	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	0 / 41 (0.00%)
occurrences (all)	0	16	0
AMYLASE INCREASED			

subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

FALL			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 6 (0.00%)	5 / 38 (13.16%)	5 / 41 (12.20%)
occurrences (all)	0	6	6
LIMB INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
COMMINUTED FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
WOUND			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 38 (2.63%)	2 / 41 (4.88%)
occurrences (all)	1	1	2
TACHYCARDIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
BUNDLE BRANCH BLOCK RIGHT			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 6 (16.67%)	4 / 38 (10.53%)	5 / 41 (12.20%)
occurrences (all)	1	4	5
DYSGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	2 / 41 (4.88%)
occurrences (all)	0	3	2
HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	8 / 38 (21.05%)	5 / 41 (12.20%)
occurrences (all)	0	8	6
HYPOAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	1 / 41 (2.44%)
occurrences (all)	0	2	1
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	6 / 38 (15.79%)	5 / 41 (12.20%)
occurrences (all)	0	9	5
PARAESTHESIA			
subjects affected / exposed	3 / 6 (50.00%)	5 / 38 (13.16%)	2 / 41 (4.88%)
occurrences (all)	3	8	2
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 6 (16.67%)	5 / 38 (13.16%)	3 / 41 (7.32%)
occurrences (all)	1	5	3
POST HERPETIC NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
AMNESIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0

DYSKINESIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
PERONEAL NERVE PALSY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
POLYNEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
RESTLESS LEGS SYNDROME			
subjects affected / exposed	1 / 6 (16.67%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
SCIATICA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	0	2	2
Blood and lymphatic system disorders			
ANAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	6 / 38 (15.79%)	5 / 41 (12.20%)
occurrences (all)	0	24	5
LEUKOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	3 / 41 (7.32%)
occurrences (all)	0	5	4
LYMPHOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	3 / 41 (7.32%)
occurrences (all)	0	5	4
NEUTROPENIA			
subjects affected / exposed	1 / 6 (16.67%)	16 / 38 (42.11%)	11 / 41 (26.83%)
occurrences (all)	1	31	18
PANCYTOPENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 6 (16.67%)	3 / 38 (7.89%)	8 / 41 (19.51%)
occurrences (all)	1	6	13
COAGULOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
HAEMOLYSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
IMMUNE THROMBOCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			

HYPOACUSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
EAR PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Eye disorders			
EYE DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EYE PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 6 (16.67%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	1	2	2
ABDOMINAL PAIN			
subjects affected / exposed	1 / 6 (16.67%)	6 / 38 (15.79%)	5 / 41 (12.20%)
occurrences (all)	1	6	5
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	1 / 41 (2.44%)
occurrences (all)	0	4	1
APHTHOUS ULCER			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
CONSTIPATION			
subjects affected / exposed	2 / 6 (33.33%)	10 / 38 (26.32%)	8 / 41 (19.51%)
occurrences (all)	2	10	8
DIARRHOEA			
subjects affected / exposed	4 / 6 (66.67%)	16 / 38 (42.11%)	9 / 41 (21.95%)
occurrences (all)	4	27	11
DRY MOUTH			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
DYSPEPSIA			
subjects affected / exposed	0 / 6 (0.00%)	4 / 38 (10.53%)	6 / 41 (14.63%)
occurrences (all)	0	6	6
FLATULENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	3 / 6 (50.00%)	22 / 38 (57.89%)	13 / 41 (31.71%)
occurrences (all)	3	35	25
ODYNOPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
STOMATITIS			
subjects affected / exposed	1 / 6 (16.67%)	5 / 38 (13.16%)	2 / 41 (4.88%)
occurrences (all)	1	6	3
VOMITING			
subjects affected / exposed	1 / 6 (16.67%)	7 / 38 (18.42%)	8 / 41 (19.51%)
occurrences (all)	1	12	11
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0

ANAL SPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	1 / 6 (16.67%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
DEFAECATION URGENCY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DIVERTICULUM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GINGIVAL DISORDER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GINGIVAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
HAEMATEMESIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
LIP DRY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0

MOUTH ULCERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NONINFECTIVE GINGIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
RECTAL DISCHARGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
DRY SKIN			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	1 / 41 (2.44%)
occurrences (all)	0	2	1
ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	4
HYPERHIDROSIS			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	1 / 41 (2.44%)
occurrences (all)	0	3	1
NIGHT SWEATS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
PRURITUS			
subjects affected / exposed	1 / 6 (16.67%)	2 / 38 (5.26%)	4 / 41 (9.76%)
occurrences (all)	1	2	4
RASH			
subjects affected / exposed	2 / 6 (33.33%)	3 / 38 (7.89%)	4 / 41 (9.76%)
occurrences (all)	2	5	5
RASH MACULO-PAPULAR			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
URTICARIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
RASH MACULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SKIN DISCOLOURATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
POLLAKIURIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	4	0
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ANURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
RENAL FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	0 / 41 (0.00%)
occurrences (all)	0	2	0

URINARY RETENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	3 / 41 (7.32%)
occurrences (all)	0	4	4
BACK PAIN			
subjects affected / exposed	1 / 6 (16.67%)	3 / 38 (7.89%)	3 / 41 (7.32%)
occurrences (all)	1	3	3
BONE PAIN			
subjects affected / exposed	2 / 6 (33.33%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	2	1	2
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 6 (33.33%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
MYALGIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	2 / 41 (4.88%)
occurrences (all)	0	3	2
CERVICAL SPINAL STENOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC DEGENERATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	0	3	2
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	1 / 6 (16.67%)	4 / 38 (10.53%)	2 / 41 (4.88%)
occurrences (all)	1	4	2
NASOPHARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	0	3	3
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	1 / 41 (2.44%)
occurrences (all)	0	3	1
PNEUMONIA			
subjects affected / exposed	1 / 6 (16.67%)	2 / 38 (5.26%)	2 / 41 (4.88%)
occurrences (all)	1	2	2
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	4 / 38 (10.53%)	2 / 41 (4.88%)
occurrences (all)	0	6	2

SINUSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	3 / 38 (7.89%)	7 / 41 (17.07%)
occurrences (all)	2	3	7
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CYTOMEGALOVIRUS VIRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
RASH PUSTULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS SITE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	3 / 6 (50.00%)	10 / 38 (26.32%)	5 / 41 (12.20%)
occurrences (all)	3	13	5
DEHYDRATION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	3 / 38 (7.89%)	1 / 41 (2.44%)
occurrences (all)	2	9	1
HYPERURICAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	3 / 38 (7.89%)	1 / 41 (2.44%)
occurrences (all)	0	3	1
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	0	2	1
HYPOCALCAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 38 (2.63%)	1 / 41 (2.44%)
occurrences (all)	1	2	1
HYPOKALAEMIA			
subjects affected / exposed	2 / 6 (33.33%)	5 / 38 (13.16%)	4 / 41 (9.76%)
occurrences (all)	2	9	6
HYPOMAGNESAEMIA			
subjects affected / exposed	3 / 6 (50.00%)	4 / 38 (10.53%)	1 / 41 (2.44%)
occurrences (all)	3	6	1
HYPOPHOSPHATAEMIA			
subjects affected / exposed	2 / 6 (33.33%)	2 / 38 (5.26%)	1 / 41 (2.44%)
occurrences (all)	2	6	1
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 38 (5.26%)	1 / 41 (2.44%)
occurrences (all)	0	4	1
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 38 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 6 (0.00%)	1 / 38 (2.63%)	0 / 41 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Arm C (Phase II Randomization): Pola+BR in DLBCL	Arm D (Phase II Randomization): BR in DLBCL	Arm E (Phase II Expansion): Pola+BG in FL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	37 / 39 (94.87%)	36 / 39 (92.31%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
HODGKIN'S DISEASE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
FLUSHING			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
HYPOTENSION			
subjects affected / exposed	2 / 39 (5.13%)	5 / 39 (12.82%)	0 / 20 (0.00%)
occurrences (all)	2	5	0
HYPERTENSION			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	2	1	2
EMBOLISM			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PALLOR			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	4 / 39 (10.26%)	6 / 39 (15.38%)	0 / 20 (0.00%)
occurrences (all)	4	8	0
CHILLS			
subjects affected / exposed	4 / 39 (10.26%)	3 / 39 (7.69%)	2 / 20 (10.00%)
occurrences (all)	5	4	2
DISCOMFORT			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
FATIGUE			
subjects affected / exposed	14 / 39 (35.90%)	14 / 39 (35.90%)	13 / 20 (65.00%)
occurrences (all)	20	17	22
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
OEDEMA			
subjects affected / exposed	2 / 39 (5.13%)	3 / 39 (7.69%)	0 / 20 (0.00%)
occurrences (all)	2	3	0
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 39 (5.13%)	2 / 39 (5.13%)	2 / 20 (10.00%)
occurrences (all)	2	2	2
PYREXIA			
subjects affected / exposed	10 / 39 (25.64%)	9 / 39 (23.08%)	2 / 20 (10.00%)
occurrences (all)	14	15	2
PAIN			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
CATHETER SITE PAIN			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE PRURITUS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
CHEST PAIN			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
EARLY SATIETY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
HYPERSENSITIVITY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
TESTICULAR PAIN			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TESTICULAR SWELLING			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	6 / 39 (15.38%)	8 / 39 (20.51%)	2 / 20 (10.00%)
occurrences (all)	6	10	2
DYSPHONIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
DYSPNOEA			
subjects affected / exposed	3 / 39 (7.69%)	2 / 39 (5.13%)	7 / 20 (35.00%)
occurrences (all)	3	2	7
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
HYPOXIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
OROPHARYNGEAL PAIN			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	2	1	2
PLEURAL EFFUSION			
subjects affected / exposed	1 / 39 (2.56%)	3 / 39 (7.69%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
PRODUCTIVE COUGH			

subjects affected / exposed	2 / 39 (5.13%)	2 / 39 (5.13%)	3 / 20 (15.00%)
occurrences (all)	2	2	4
RHINORRHOEA			
subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
THROAT IRRITATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
BRONCHOSPASM			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NASAL DISCHARGE DISCOLOURATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORGANISING PNEUMONIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

RHINITIS ALLERGIC			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS PAIN			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
TACHYPNOEA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	3 / 39 (7.69%)	2 / 39 (5.13%)	1 / 20 (5.00%)
occurrences (all)	3	2	1
DEPRESSION			
subjects affected / exposed	1 / 39 (2.56%)	3 / 39 (7.69%)	2 / 20 (10.00%)
occurrences (all)	1	3	2
INSOMNIA			
subjects affected / exposed	3 / 39 (7.69%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	3	0	2
CONFUSIONAL STATE			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
DELIRIUM			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
IRRITABILITY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SUICIDAL IDEATION			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	6
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	3
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	1	1	6
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	5
BLOOD CREATININE INCREASED			
subjects affected / exposed	2 / 39 (5.13%)	4 / 39 (10.26%)	3 / 20 (15.00%)
occurrences (all)	2	6	3
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
LIPASE INCREASED			
subjects affected / exposed	3 / 39 (7.69%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	5	0	1
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 39 (2.56%)	3 / 39 (7.69%)	2 / 20 (10.00%)
occurrences (all)	1	5	6
NEUTROPHIL COUNT DECREASED			

subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
PLATELET COUNT DECREASED			
subjects affected / exposed	4 / 39 (10.26%)	2 / 39 (5.13%)	1 / 20 (5.00%)
occurrences (all)	5	5	1
WEIGHT DECREASED			
subjects affected / exposed	5 / 39 (12.82%)	2 / 39 (5.13%)	2 / 20 (10.00%)
occurrences (all)	5	2	3
WEIGHT INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 39 (2.56%)	4 / 39 (10.26%)	3 / 20 (15.00%)
occurrences (all)	1	6	7
AMYLASE INCREASED			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
TROPONIN INCREASED			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
LIMB INJURY			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COMMINUTED FRACTURE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
WOUND			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Cardiac disorders			

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 39 (0.00%)	3 / 39 (7.69%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
TACHYCARDIA			
subjects affected / exposed	2 / 39 (5.13%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	3	2	0
BUNDLE BRANCH BLOCK RIGHT			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	5 / 39 (12.82%)	3 / 39 (7.69%)	3 / 20 (15.00%)
occurrences (all)	5	3	3
DYSGEUSIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	3 / 20 (15.00%)
occurrences (all)	1	0	3
HEADACHE			
subjects affected / exposed	3 / 39 (7.69%)	2 / 39 (5.13%)	6 / 20 (30.00%)
occurrences (all)	3	3	6
HYPOAESTHESIA			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	5
NEUROPATHY PERIPHERAL			
subjects affected / exposed	9 / 39 (23.08%)	1 / 39 (2.56%)	5 / 20 (25.00%)
occurrences (all)	10	1	5
PARAESTHESIA			

subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	6 / 39 (15.38%)	0 / 39 (0.00%)	3 / 20 (15.00%)
occurrences (all)	7	0	3
POST HERPETIC NEURALGIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SYNCOPE			
subjects affected / exposed	2 / 39 (5.13%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	2	3	0
AMNESIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSKINESIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
NEURALGIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
PERONEAL NERVE PALSY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
POLYNEUROPATHY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
SCIATICA			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUS HEADACHE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SOMNOLENCE			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
TASTE DISORDER			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	19 / 39 (48.72%)	10 / 39 (25.64%)	3 / 20 (15.00%)
occurrences (all)	28	13	7
LEUKOPENIA			
subjects affected / exposed	5 / 39 (12.82%)	4 / 39 (10.26%)	0 / 20 (0.00%)
occurrences (all)	19	6	0
LYMPHOPENIA			
subjects affected / exposed	5 / 39 (12.82%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	6	0	5
NEUTROPENIA			
subjects affected / exposed	21 / 39 (53.85%)	14 / 39 (35.90%)	6 / 20 (30.00%)
occurrences (all)	63	27	10
PANCYTOPENIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	19 / 39 (48.72%)	11 / 39 (28.21%)	4 / 20 (20.00%)
occurrences (all)	50	18	4
COAGULOPATHY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HAEMOLYSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LYMPHADENOPATHY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
IMMUNE THROMBOCYTOPENIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
HYPOACUSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
EYE DISCHARGE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE PRURITUS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
GLAUCOMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
ABDOMINAL PAIN			
subjects affected / exposed	3 / 39 (7.69%)	3 / 39 (7.69%)	0 / 20 (0.00%)
occurrences (all)	3	3	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	5 / 39 (12.82%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	5	2	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
CONSTIPATION			
subjects affected / exposed	7 / 39 (17.95%)	8 / 39 (20.51%)	7 / 20 (35.00%)
occurrences (all)	8	9	11
DIARRHOEA			
subjects affected / exposed	16 / 39 (41.03%)	11 / 39 (28.21%)	10 / 20 (50.00%)
occurrences (all)	28	13	22
DRY MOUTH			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	3 / 20 (15.00%)
occurrences (all)	1	1	3
DYSPEPSIA			
subjects affected / exposed	3 / 39 (7.69%)	2 / 39 (5.13%)	3 / 20 (15.00%)
occurrences (all)	4	2	3
FLATULENCE			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
GASTROOESOPHAGEAL REFLUX DISEASE			

subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
NAUSEA			
subjects affected / exposed	12 / 39 (30.77%)	16 / 39 (41.03%)	11 / 20 (55.00%)
occurrences (all)	14	19	21
ODYNOPHAGIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	3 / 39 (7.69%)	4 / 39 (10.26%)	1 / 20 (5.00%)
occurrences (all)	4	4	1
VOMITING			
subjects affected / exposed	7 / 39 (17.95%)	5 / 39 (12.82%)	8 / 20 (40.00%)
occurrences (all)	11	8	10
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ANAL SPASM			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
COLITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DEFAECATION URGENCY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DIVERTICULUM			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GINGIVAL DISORDER			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
GINGIVAL PAIN			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
HAEMATEMESIS			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
HAEMORRHOIDS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LIP DRY			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
MOUTH ULCERATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NONINFECTIVE GINGIVITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL DISCHARGE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	3 / 20 (15.00%)
occurrences (all)	0	1	3
DRY SKIN			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

ERYTHEMA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
PRURITUS			
subjects affected / exposed	5 / 39 (12.82%)	4 / 39 (10.26%)	1 / 20 (5.00%)
occurrences (all)	6	5	1
RASH			
subjects affected / exposed	2 / 39 (5.13%)	5 / 39 (12.82%)	3 / 20 (15.00%)
occurrences (all)	2	5	5
RASH MACULO-PAPULAR			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
URTICARIA			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
DERMATITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RASH MACULAR			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SKIN DISCOLOURATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
POLLAKIURIA			

subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
URINARY INCONTINENCE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
ANURIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HAEMATURIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
RENAL FAILURE			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	5 / 39 (12.82%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	5	1	4
BACK PAIN			
subjects affected / exposed	1 / 39 (2.56%)	4 / 39 (10.26%)	3 / 20 (15.00%)
occurrences (all)	1	4	3
BONE PAIN			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	3 / 20 (15.00%)
occurrences (all)	2	1	4
MUSCULOSKELETAL PAIN			

subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MYALGIA			
subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
PAIN IN EXTREMITY			
subjects affected / exposed	2 / 39 (5.13%)	2 / 39 (5.13%)	1 / 20 (5.00%)
occurrences (all)	2	2	2
CERVICAL SPINAL STENOSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
GROIN PAIN			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
INTERVERTEBRAL DISC DEGENERATION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MUSCLE SPASMS			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
NECK PAIN			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
BRONCHITIS			

subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HERPES VIRUS INFECTION			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
HERPES ZOSTER			
subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
NASOPHARYNGITIS			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
ORAL HERPES			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
PNEUMONIA			
subjects affected / exposed	3 / 39 (7.69%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	1 / 39 (2.56%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	1	1	2
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	5 / 20 (25.00%)
occurrences (all)	4	1	5
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 39 (2.56%)	2 / 39 (5.13%)	2 / 20 (10.00%)
occurrences (all)	1	2	2
CANDIDA INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CELLULITIS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
CYTOMEGALOVIRUS VIRAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
FOLLICULITIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INFECTION			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
ORAL CANDIDIASIS			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	3
RASH PUSTULAR			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			

subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS SITE INFECTION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	10 / 39 (25.64%)	8 / 39 (20.51%)	6 / 20 (30.00%)
occurrences (all)	11	8	7
DEHYDRATION			
subjects affected / exposed	2 / 39 (5.13%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
HYPERCALCAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	2 / 39 (5.13%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
HYPERURICAEMIA			
subjects affected / exposed	1 / 39 (2.56%)	0 / 39 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
HYPOALBUMINAEMIA			
subjects affected / exposed	5 / 39 (12.82%)	2 / 39 (5.13%)	1 / 20 (5.00%)
occurrences (all)	7	2	1
HYPOCALCAEMIA			
subjects affected / exposed	3 / 39 (7.69%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	5	1	5
HYPOKALAEMIA			
subjects affected / exposed	4 / 39 (10.26%)	3 / 39 (7.69%)	3 / 20 (15.00%)
occurrences (all)	7	3	9
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 39 (2.56%)	4 / 39 (10.26%)	4 / 20 (20.00%)
occurrences (all)	1	5	4
HYPOPHOSPHATAEMIA			
subjects affected / exposed	2 / 39 (5.13%)	1 / 39 (2.56%)	2 / 20 (10.00%)
occurrences (all)	3	1	6

HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	1 / 39 (2.56%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
HYPONATRAEMIA			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	4
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 39 (0.00%)	0 / 39 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Arm F (Phase II Expansion): Pola+BG in DLBCL	Arm G+H (Phase II NF Cohort): Pola+BR in DLBCL	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 20 (95.00%)	103 / 106 (97.17%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
HODGKIN'S DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
TUMOUR PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			

DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
FLUSHING			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
HYPOTENSION			
subjects affected / exposed	3 / 20 (15.00%)	10 / 106 (9.43%)	
occurrences (all)	4	12	
HYPERTENSION			
subjects affected / exposed	2 / 20 (10.00%)	1 / 106 (0.94%)	
occurrences (all)	2	1	
EMBOLISM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
PALLOR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
PHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	3 / 20 (15.00%)	12 / 106 (11.32%)	
occurrences (all)	3	13	
CHILLS			
subjects affected / exposed	5 / 20 (25.00%)	2 / 106 (1.89%)	
occurrences (all)	5	2	
DISCOMFORT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
FATIGUE			

subjects affected / exposed	12 / 20 (60.00%)	22 / 106 (20.75%)	
occurrences (all)	15	25	
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
OEDEMA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 20 (15.00%)	6 / 106 (5.66%)	
occurrences (all)	3	7	
PYREXIA			
subjects affected / exposed	8 / 20 (40.00%)	22 / 106 (20.75%)	
occurrences (all)	9	27	
PAIN			
subjects affected / exposed	0 / 20 (0.00%)	5 / 106 (4.72%)	
occurrences (all)	0	5	
CATHETER SITE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
CATHETER SITE PRURITUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
CHEST DISCOMFORT			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences (all)	1	2	
CHEST PAIN			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
EARLY SATIETY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
GAIT DISTURBANCE			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
PERIPHERAL SWELLING			

subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
Immune system disorders			
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
HYPERSENSITIVITY			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	2	
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
TESTICULAR PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
TESTICULAR SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
VAGINAL HAEMORRHAGE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	3 / 20 (15.00%)	13 / 106 (12.26%)	
occurrences (all)	3	16	
DYSPHONIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
DYSPNOEA			
subjects affected / exposed	6 / 20 (30.00%)	3 / 106 (2.83%)	
occurrences (all)	7	4	
DYSPNOEA EXERTIONAL			

subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences (all)	1	2	
HYPOXIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
NASAL CONGESTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	5 / 106 (4.72%)	
occurrences (all)	0	6	
PLEURAL EFFUSION			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	3	
RHINORRHOEA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
THROAT IRRITATION			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	3	
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
BRONCHOSPASM			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
HAEMOPTYSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
HICCUPS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
NASAL DISCHARGE			

DISCOLOURATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
ORGANISING PNEUMONIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
PNEUMONITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	2	
PULMONARY OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
RHINITIS ALLERGIC			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
SINUS CONGESTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
SINUS PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
TACHYPNOEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	2 / 20 (10.00%)	4 / 106 (3.77%)	
occurrences (all)	2	4	
DEPRESSION			
subjects affected / exposed	2 / 20 (10.00%)	1 / 106 (0.94%)	
occurrences (all)	2	1	
INSOMNIA			

subjects affected / exposed	1 / 20 (5.00%)	8 / 106 (7.55%)	
occurrences (all)	1	10	
CONFUSIONAL STATE			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
DELIRIUM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
IRRITABILITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
SUICIDAL IDEATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)	
occurrences (all)	0	4	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	5 / 106 (4.72%)	
occurrences (all)	0	6	
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	7 / 106 (6.60%)	
occurrences (all)	0	11	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)	
occurrences (all)	0	9	
GAMMA-GLUTAMYLTRANSFERASE INCREASED			

subjects affected / exposed	0 / 20 (0.00%)	6 / 106 (5.66%)	
occurrences (all)	0	8	
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	2	
LIPASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)	
occurrences (all)	0	7	
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	8 / 106 (7.55%)	
occurrences (all)	0	16	
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	2 / 20 (10.00%)	14 / 106 (13.21%)	
occurrences (all)	2	37	
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	8 / 106 (7.55%)	
occurrences (all)	0	11	
WEIGHT DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	14 / 106 (13.21%)	
occurrences (all)	1	14	
WEIGHT INCREASED			
subjects affected / exposed	2 / 20 (10.00%)	2 / 106 (1.89%)	
occurrences (all)	2	2	
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	9 / 106 (8.49%)	
occurrences (all)	1	29	
AMYLASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)	
occurrences (all)	0	4	
BLOOD CALCIUM DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	

BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences (all)	1	2	
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
TRANSAMINASES INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
TROPONIN I INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
TROPONIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	1 / 20 (5.00%)	3 / 106 (2.83%)	
occurrences (all)	2	4	
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
LIMB INJURY			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
ARTHROPOD BITE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
COMMINUTED FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
WOUND			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	2	
TACHYCARDIA			
subjects affected / exposed	1 / 20 (5.00%)	6 / 106 (5.66%)	
occurrences (all)	1	6	
BUNDLE BRANCH BLOCK RIGHT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 20 (5.00%)	10 / 106 (9.43%)	
occurrences (all)	1	11	
DYSGEUSIA			

subjects affected / exposed	1 / 20 (5.00%)	5 / 106 (4.72%)	
occurrences (all)	1	5	
HEADACHE			
subjects affected / exposed	3 / 20 (15.00%)	12 / 106 (11.32%)	
occurrences (all)	4	14	
HYPOAESTHESIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 20 (5.00%)	15 / 106 (14.15%)	
occurrences (all)	1	16	
PARAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)	
occurrences (all)	0	4	
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	2 / 20 (10.00%)	5 / 106 (4.72%)	
occurrences (all)	2	6	
POST HERPETIC NEURALGIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 106 (0.00%)	
occurrences (all)	2	0	
SYNCOPE			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
AMNESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
DYSKINESIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
LETHARGY			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
NEURALGIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
PERONEAL NERVE PALSY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
POLYNEUROPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
SCIATICA			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
SINUS HEADACHE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
SOMNOLENCE			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
TASTE DISORDER			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
TREMOR			
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)	
occurrences (all)	0	4	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	5 / 20 (25.00%)	27 / 106 (25.47%)	
occurrences (all)	6	35	
LEUKOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	7 / 106 (6.60%)	
occurrences (all)	0	17	
LYMPHOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	5 / 106 (4.72%)	
occurrences (all)	0	7	

NEUTROPENIA			
subjects affected / exposed	6 / 20 (30.00%)	35 / 106 (33.02%)	
occurrences (all)	30	73	
PANCYTOPENIA			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences (all)	1	2	
THROMBOCYTOPENIA			
subjects affected / exposed	7 / 20 (35.00%)	19 / 106 (17.92%)	
occurrences (all)	10	40	
COAGULOPATHY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
HAEMOLYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
LYMPHADENOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
IMMUNE THROMBOCYTOPENIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
HYPOACUSIS			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
EAR PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
Eye disorders			

EYE DISCHARGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
EYE PRURITUS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
GLAUCOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
OCULAR HYPERAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
VISION BLURRED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	2 / 20 (10.00%)	1 / 106 (0.94%)	
occurrences (all)	2	1	
ABDOMINAL PAIN			
subjects affected / exposed	2 / 20 (10.00%)	12 / 106 (11.32%)	
occurrences (all)	2	14	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	2 / 20 (10.00%)	0 / 106 (0.00%)	
occurrences (all)	2	0	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 20 (0.00%)	6 / 106 (5.66%)	
occurrences (all)	0	7	
APHTHOUS ULCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
CONSTIPATION			
subjects affected / exposed	9 / 20 (45.00%)	20 / 106 (18.87%)	
occurrences (all)	10	27	
DIARRHOEA			

subjects affected / exposed	11 / 20 (55.00%)	36 / 106 (33.96%)		
occurrences (all)	18	48		
DRY MOUTH				
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)		
occurrences (all)	0	4		
DYSPEPSIA				
subjects affected / exposed	0 / 20 (0.00%)	5 / 106 (4.72%)		
occurrences (all)	0	6		
FLATULENCE				
subjects affected / exposed	2 / 20 (10.00%)	1 / 106 (0.94%)		
occurrences (all)	2	1		
GASTROOESOPHAGEAL REFLUX DISEASE				
subjects affected / exposed	2 / 20 (10.00%)	3 / 106 (2.83%)		
occurrences (all)	2	3		
NAUSEA				
subjects affected / exposed	11 / 20 (55.00%)	34 / 106 (32.08%)		
occurrences (all)	16	38		
ODYNOPHAGIA				
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)		
occurrences (all)	0	4		
STOMATITIS				
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)		
occurrences (all)	1	0		
VOMITING				
subjects affected / exposed	8 / 20 (40.00%)	17 / 106 (16.04%)		
occurrences (all)	10	18		
ABDOMINAL DISCOMFORT				
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)		
occurrences (all)	0	1		
ANAL SPASM				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
COLITIS				
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)		
occurrences (all)	0	1		

DEFAECATION URGENCY				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
DIVERTICULUM				
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)		
occurrences (all)	1	0		
DYSPHAGIA				
subjects affected / exposed	1 / 20 (5.00%)	3 / 106 (2.83%)		
occurrences (all)	1	3		
GINGIVAL BLEEDING				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
GINGIVAL DISORDER				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
GINGIVAL PAIN				
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)		
occurrences (all)	0	1		
HAEMATEMESIS				
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)		
occurrences (all)	1	0		
HAEMATOCHEZIA				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
HAEMORRHOIDS				
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)		
occurrences (all)	1	2		
LIP DRY				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
MOUTH ULCERATION				
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)		
occurrences (all)	0	2		
NONINFECTIVE GINGIVITIS				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		

RECTAL DISCHARGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	2 / 20 (10.00%)	1 / 106 (0.94%)	
occurrences (all)	2	1	
DRY SKIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
ERYTHEMA			
subjects affected / exposed	2 / 20 (10.00%)	5 / 106 (4.72%)	
occurrences (all)	2	10	
HYPERHIDROSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
NIGHT SWEATS			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
PRURITUS			
subjects affected / exposed	0 / 20 (0.00%)	8 / 106 (7.55%)	
occurrences (all)	0	9	
RASH			
subjects affected / exposed	3 / 20 (15.00%)	5 / 106 (4.72%)	
occurrences (all)	3	8	
RASH MACULO-PAPULAR			
subjects affected / exposed	2 / 20 (10.00%)	2 / 106 (1.89%)	
occurrences (all)	2	2	
URTICARIA			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	2	
DERMATITIS			

subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
RASH MACULAR			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
SKIN DISCOLOURATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences (all)	1	2	
POLLAKIURIA			
subjects affected / exposed	2 / 20 (10.00%)	1 / 106 (0.94%)	
occurrences (all)	2	1	
URINARY INCONTINENCE			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	3	
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 20 (0.00%)	4 / 106 (3.77%)	
occurrences (all)	0	4	
ANURIA			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
HAEMATURIA			
subjects affected / exposed	1 / 20 (5.00%)	3 / 106 (2.83%)	
occurrences (all)	1	4	
RENAL FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
URINARY RETENTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			

ARTHRALGIA				
subjects affected / exposed	1 / 20 (5.00%)	6 / 106 (5.66%)		
occurrences (all)	1	6		
BACK PAIN				
subjects affected / exposed	2 / 20 (10.00%)	7 / 106 (6.60%)		
occurrences (all)	2	8		
BONE PAIN				
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)		
occurrences (all)	1	2		
MUSCULAR WEAKNESS				
subjects affected / exposed	1 / 20 (5.00%)	3 / 106 (2.83%)		
occurrences (all)	1	3		
MUSCULOSKELETAL PAIN				
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)		
occurrences (all)	0	1		
MYALGIA				
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)		
occurrences (all)	0	3		
PAIN IN EXTREMITY				
subjects affected / exposed	3 / 20 (15.00%)	4 / 106 (3.77%)		
occurrences (all)	3	4		
CERVICAL SPINAL STENOSIS				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
GROIN PAIN				
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)		
occurrences (all)	1	1		
INTERVERTEBRAL DISC DEGENERATION				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
MUSCLE SPASMS				
subjects affected / exposed	1 / 20 (5.00%)	3 / 106 (2.83%)		
occurrences (all)	1	3		
MUSCLE TIGHTNESS				

subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
NECK PAIN			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	2	1	
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	2	
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
HERPES ZOSTER			
subjects affected / exposed	3 / 20 (15.00%)	0 / 106 (0.00%)	
occurrences (all)	4	0	
NASOPHARYNGITIS			
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)	
occurrences (all)	1	1	
ORAL HERPES			
subjects affected / exposed	0 / 20 (0.00%)	2 / 106 (1.89%)	
occurrences (all)	0	2	
PNEUMONIA			
subjects affected / exposed	0 / 20 (0.00%)	6 / 106 (5.66%)	
occurrences (all)	0	6	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
SINUSITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	

UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	2 / 20 (10.00%)	7 / 106 (6.60%)		
occurrences (all)	3	10		
URINARY TRACT INFECTION				
subjects affected / exposed	2 / 20 (10.00%)	7 / 106 (6.60%)		
occurrences (all)	2	8		
CANDIDA INFECTION				
subjects affected / exposed	1 / 20 (5.00%)	1 / 106 (0.94%)		
occurrences (all)	1	1		
CELLULITIS				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
CLOSTRIDIUM DIFFICILE INFECTION				
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)		
occurrences (all)	1	0		
CYSTITIS				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
CYTOMEGALOVIRUS INFECTION				
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)		
occurrences (all)	1	0		
CYTOMEGALOVIRUS VIRAEMIA				
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)		
occurrences (all)	1	0		
EAR INFECTION				
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)		
occurrences (all)	2	0		
ESCHERICHIA URINARY TRACT INFECTION				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
FOLLICULITIS				
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)		
occurrences (all)	0	0		
INFECTION				

subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 106 (0.94%)	
occurrences (all)	0	1	
RASH PUSTULAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
SKIN INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	
VASCULAR ACCESS SITE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	8 / 20 (40.00%)	27 / 106 (25.47%)	
occurrences (all)	10	30	
DEHYDRATION			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences (all)	1	2	
HYPERCALCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
HYPERURICAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
HYPOALBUMINAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
HYPOCALCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
HYPOKALAEMIA			
subjects affected / exposed	5 / 20 (25.00%)	15 / 106 (14.15%)	
occurrences (all)	5	20	
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	13 / 106 (12.26%)	
occurrences (all)	1	18	
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	2 / 106 (1.89%)	
occurrences (all)	1	5	
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
HYPONATRAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 106 (2.83%)	
occurrences (all)	0	3	
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
MALNUTRITION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 106 (0.00%)	
occurrences (all)	0	0	
VITAMIN D DEFICIENCY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 106 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 April 2015	- Amendment to the Phase Ib portion to be a safety run-in at the 1.8 mg/kg polatuzumab vedotin dose for each lymphoma histology. The original design for a Phase Ib dose-escalation of polatuzumab vedotin to 2.4 mg/kg was modified following the issuance of a Partial Clinical Hold at the 2.4 mg/kg dose by the U.S. Food and Drug Administration in September 2014. - Adoption of the new Lugano 2014 response criteria (Cheson et al. 2014) for NHL (which were published after finalization the first protocol), for evaluating CR by PET at the primary response assessment by IRC.
14 September 2015	Modification of the Lugano 2014 response criteria; Update to eligibility criteria; Inclusion of gastrointestinal perforations as an identified risk associated with obinutuzumab treatment; Updates to the guidelines for monitoring of hepatitis B reactivation for patients with occult or prior hepatitis B virus infection
11 July 2017	The primary purpose of this amendment was to include second malignancies as a Clinical Study Report: polatuzumab vedotin - F. Hoffmann-La Roche Ltd Protocol GO29365 Report Number 1078954 108 AESI/non-serious expedited AE requiring expedited reporting, and to require indefinite reporting of second malignancies (even if the study has ended) for patients enrolled in the obinutuzumab containing cohorts (pola+BG).
16 November 2017	The primary purpose of this amendment was to add an additional cohort of 2030 patients (Arm G) with R/R DLBCL who will receive a new lyophilized formulation of polatuzumab vedotin (140 mg/vial) in combination with BR, in order to gain clinical experience with this combination in R/R DLBCL in terms of PK and safety. Additionally, protocol v5 introduced the analysis of PFS and DOR by IRC for the DLBCL cohorts as requested by the U.S. FDA
31 May 2018	The primary purpose of this amendment was the expansion of Arm G, adding 10 patients with R/R DLBCL with one prior line of therapy (i.e., second line [2L]) to evaluate the efficacy of polatuzumab vedotin (lyophilized) in combination with BR. Protocol v6 also added the analysis of IRC assessed best overall response for the DLBCL cohorts.
23 March 2020	Updated reporting requirements for cases of second malignancies to be reported indefinitely for all enrolled subjects ; Updated reporting requirements for cases of accidental overdose or medication error, which are no longer required to be reported within 24 hours after learning of the event; Safety language
07 October 2020	The primary purpose of this amendment was to add a new arm (Arm H) to the Phase II lyophilized formulation Cohort to enroll approximately 60 patients with R/R DLBCL who were to receive the 140- mg/vial lyophilized formulation of polatuzumab vedotin in addition to BR in order to gain supportive clinical experience with the combination of polatuzumab vedotin (lyophilized formulation) with BR.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported