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

Summary

EudraCT number	2015-001999-22
Trial protocol	ES
Global end of trial date	15 December 2021

Results information

Result version number	v1
This version publication date	18 December 2022
First version publication date	18 December 2022

Trial information

Trial identification

Sponsor protocol code	GO29834

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02600897
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. 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, genentech@druginfo.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	15 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate the safety, tolerability and determine the recommended phase 2 dose (RP2D) of polatuzumab vedotin (pola) and lenalidomide (Len) when given in combination with a fixed dose of obinutuzumab (G) in participants with follicular lymphoma (FL) and the RP2D of len when given in combination with a fixed dose of pola and rituximab (R) in participants with diffuse large B-cell lymphoma (DLBCL). The study also evaluated the efficacy of induction treatment with G + Pola +Len in relapsed or refractory (R/R) FL and R+ Pola + Len in R/R DLBCL.

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	24 March 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 57
Country: Number of subjects enrolled	United Kingdom: 29
Country: Number of subjects enrolled	United States: 28
Worldwide total number of subjects	114
EEA total number of subjects	57

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)	50
From 65 to 84 years	62
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

A total of 114 participants with R/R FL or DLBCL were enrolled in this study at 28 investigative sites in Spain, United Kingdom and United States from 24 March 2016 to 15 December 2021. The study consisted of two phases: dose-escalation and dose-expansion phase. All eligible participants in both phases received induction & post-induction therapy.

Pre-assignment

Screening details:

Participants were enrolled in Phase Ib & Phase II study to receive polatuzumab vedotin + lenalidomide & fixed doses of rituximab/obinutuzumab. Of the 114 enrolled participants, 113 participants received at least one dose of the study drug & their intended treatment. 1 participant withdrew consent prior to receiving any study 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	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL

Arm description:

Participants with FL received lenalidomide, 10 milligrams (mg) capsules orally once daily (QD) on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as intravenous (IV) infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 milligrams per kilogram (mg/kg), IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved complete response (CR), partial response (PR), or stable disease (SD) at end of induction (EOI) received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

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

Dosage and administration details:

Participants received lenalidomide oral capsules 10 milligrams (mg) on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in dose escalation phase followed by maintenance treatment (only for R/R FL participants with CR, PR or SD) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 12 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received polatuzumab vedotin via IV infusion at doses of 1.4 milligrams per kilogram (mg/kg) on Day 1 of each 28-day cycle for up to 6 cycles during induction treatment.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received a fixed dose of obinutuzumab, 1000 mg via intravenous (IV) infusion administered on Days 1, 8 and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 followed by maintenance treatment (only for participants with CR, PR or SD) at a dose of 1000 mg via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 24 months.

Arm title	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL

Arm description:

Participants with FL received lenalidomide, 10 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.8 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

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

Dosage and administration details:

Participants received lenalidomide oral capsules 10 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in dose escalation phase followed by maintenance treatment (only for R/R FL participants with CR, PR or SD) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 12 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received polatuzumab vedotin via IV infusion at doses of 1.8 mg/kg on Day 1 of each 28-day cycle for up to 6 cycles during induction treatment.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received a fixed dose of obinutuzumab, 1000 mg via IV infusion administered on Days 1, 8 and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 followed by maintenance treatment (only for participants with CR, PR or SD) at a dose of 1000 mg via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 24 months.

Arm title	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL

Arm description:

Participants with FL received lenalidomide, 15 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During

maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

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

Dosage and administration details:

Participants received lenalidomide oral capsules 15 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in dose escalation phase followed by maintenance treatment (only for R/R FL participants with CR, PR or SD) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 12 months.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received a fixed dose of obinutuzumab, 1000 mg via IV infusion administered on Days 1, 8 and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 followed by maintenance treatment (only for participants with CR, PR or SD) at a dose of 1000 mg via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 24 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received polatuzumab vedotin via IV infusion at doses of 1.8 mg/kg on Day 1 of each 28-day cycle for up to 6 cycles during induction treatment.

Arm title	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL

Arm description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

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

Dosage and administration details:

Participants received lenalidomide oral capsules, 20 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in dose escalation phase followed by maintenance treatment (only for R/R FL participants with CR, PR or SD) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 12 months.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received a fixed dose of obinutuzumab, 1000 mg via IV infusion administered on Days 1, 8 and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 followed by maintenance treatment (only for participants with CR, PR or SD) at a dose of 1000 mg via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 24 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received polatuzumab vedotin via IV infusion at doses of 1.4 mg/kg on Day 1 of each 28-day cycle for up to 6 cycles during induction treatment.

Arm title	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL

Arm description:

Participants with DLBCL received lenalidomide, 10 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 milligrams per square meter (mg/m^2), as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

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

Dosage and administration details:

All participants received lenalidomide oral capsules 10 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in dose escalation phase followed by consolidation treatment (only for participants with CR or PR) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a fixed dose of rituximab, 375 mg/m^2 via intravenous (IV) infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R DLBCL received polatuzumab vedotin via IV infusion at dose 1.8 mg/kg on Day 1

of each 28-day cycle for up to 6 cycles during induction treatment.

Arm title	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL

Arm description:

Participants with DLBCL received lenalidomide, 15 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

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

Dosage and administration details:

All participants received lenalidomide oral capsules 15 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in dose escalation phase followed by consolidation treatment (only for participants with CR or PR) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a fixed dose of rituximab, 375 mg/m^2 via IV infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R DLBCL received polatuzumab vedotin via IV infusion at dose 1.8 mg/kg on Day 1 of each 28-day cycle for up to 6 cycles during induction treatment.

Arm title	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL

Arm description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Arm type	Experimental

Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received lenalidomide oral capsules 20 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in dose escalation phase followed by consolidation treatment (only for participants with CR or PR) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a fixed dose of rituximab, 375 mg/m^2 via IV infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R DLBCL received polatuzumab vedotin via IV infusion at dose 1.8 mg/kg on Day 1 of each 28-day cycle for up to 6 cycles during induction treatment.

Arm title	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL

Arm description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

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

Dosage and administration details:

Participants received lenalidomide oral capsules, 20 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in expansion phase followed by maintenance treatment (only for participants with CR or PR) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 12 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received polatuzumab vedotin via IV infusion at dose 1.4 mg/kg on Day 1 of

each 28-day cycle for up to 6 cycles during induction treatment.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R FL received a fixed dose of obinutuzumab, 1000 mg via IV infusion administered on Days 1, 8 and 15 of Cycle 1 and on Day 1 of Cycles 2 to 6 followed by maintenance treatment (only for participants with CR, PR or SD) at a dose of 1000 mg via IV infusion on Day 1 of every other month for up to 24 months until disease progression or unacceptable toxicity.

Arm title	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL

Arm description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

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

Dosage and administration details:

Participants received lenalidomide oral capsules, 20 mg on Days 1 to 21 of each 28-day cycle for up to 6 Cycles in expansion phase followed by consolidation treatment (only for participants with CR or PR) at a dose of 10 mg once daily on Days 1 to 21 of each month (1 month=28 days). Post-induction lenalidomide was continued until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a fixed dose of rituximab, 375 mg/m^2 via IV infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 6 months.

Investigational medicinal product name	Polatuzumab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with R/R DLBCL received polatuzumab vedotin via IV infusion at dose 1.8 mg/kg on Day 1 of each 28-day cycle for up to 6 cycles during induction treatment.

Number of subjects in period 1	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL
Started	3	4	3
Intent-to-Treat Population	3	4	3
Safety-evaluable Population	3	4	3
Pharmacokinetic-evaluable Population	3	4	3
Immunogenicity-evaluable Population	3	4	3
Completed	1	2	2
Not completed	2	2	1
Adverse event, serious fatal	1	2	1
Consent withdrawn by subject	-	-	-
Reason Not Specified	-	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL
Started	6	3	5
Intent-to-Treat Population	6	3	5
Safety-evaluable Population	6	3	5
Pharmacokinetic-evaluable Population	6	3	5
Immunogenicity-evaluable Population	6	3	5
Completed	4	0	3
Not completed	2	3	2
Adverse event, serious fatal	2	3	2
Consent withdrawn by subject	-	-	-
Reason Not Specified	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Started	10	40	40
Intent-to-Treat Population	10	40	40
Safety-evaluable Population	10	40	39
Pharmacokinetic-evaluable Population	10	40	39
Immunogenicity-evaluable Population	10	39	38
Completed	0	28	17
Not completed	10	12	23
Adverse event, serious fatal	10	7	20
Consent withdrawn by subject	-	4	2
Reason Not Specified	-	-	1

Lost to follow-up	-	1	-

Reporting groups

Reporting group title	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 10 milligrams (mg) capsules orally once daily (QD) on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as intravenous (IV) infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 milligrams per kilogram (mg/kg), IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved complete response (CR), partial response (PR), or stable disease (SD) at end of induction (EOI) received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 10 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.8 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 15 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 10 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 milligrams per square meter (mg/m^2), as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 15 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1

cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL
Number of subjects	3	4	3
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	61.3	72.5	56.0
standard deviation	± 6.1	± 8.1	± 3.5
Sex: Female, Male Units:			
Female	2	3	2
Male	1	1	1
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	4	2
Not Stated	0	0	1
Unknown	0	0	0

Race Units: Subjects			
Asian	0	0	0
White	3	4	3
Unknown or Not Reported	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
More than one race	0	0	0

Reporting group values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL
Number of subjects	6	3	5
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	58.3	59.7	62.0
standard deviation	± 12.0	± 6.5	± 14.9
Sex: Female, Male Units:			
Female	4	0	1
Male	2	3	4
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	6	3	4
Not Stated	0	0	0
Unknown	0	0	0
Race Units: Subjects			
Asian	0	0	0
White	6	3	5
Unknown or Not Reported	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
More than one race	0	0	0

Reporting group values	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Number of subjects	10	40	40
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	61.4	61.6	68.4
standard deviation	± 14.2	± 11.2	± 12.8
Sex: Female, Male Units:			
Female	4	12	14
Male	6	28	26
Ethnicity Units: Subjects			
Hispanic or Latino	3	4	4
Not Hispanic or Latino	7	34	34
Not Stated	0	2	1
Unknown	0	0	1
Race Units: Subjects			
Asian	0	1	1
White	10	36	38
Unknown or Not Reported	0	3	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
More than one race	0	0	0

Reporting group values	Total		
Number of subjects	114		
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units:			
Female	42		
Male	72		
Ethnicity Units: Subjects			
Hispanic or Latino	12		
Not Hispanic or Latino	97		
Not Stated	4		
Unknown	1		
Race Units: Subjects			
Asian	2		
White	108		
Unknown or Not Reported	4		
American Indian or Alaska Native	0		
Native Hawaiian or Other Pacific Islander	0		

Black or African American	0		
More than one race	0		

End points reporting groups

Reporting group title	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 10 milligrams (mg) capsules orally once daily (QD) on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as intravenous (IV) infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 milligrams per kilogram (mg/kg), IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved complete response (CR), partial response (PR), or stable disease (SD) at end of induction (EOI) received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 10 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.8 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 15 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 10 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 milligrams per square meter (mg/m^2), as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 15 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Primary: Percentage of Participants with Dose-Limiting Toxicities (DLTs)

End point title	Percentage of Participants with Dose-Limiting Toxicities

End point description:

A DLT was defined as any one of the following toxicities occurring during the first cycle of treatment and assessed by the investigator as related to study treatment: Any adverse event of any grade that lead to a delay of > 14 days in the start of the next treatment cycle, Grade 3 or 4 non-hematologic adverse events with few exceptions; increase in hepatic transaminase > 3 x baseline and an increase in direct bilirubin > 2 x upper limits of normal (ULN), without any findings of cholestasis or jaundice, or signs of hepatic dysfunction, and in the absence of other contributory factors; hematologic adverse events that met a few protocol specified criteria. DLTs were assessed according to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 4.0 (NCI CTCAE v4.0). The safety-evaluable population included all participants who received at least one dose of any component of the combination.

End point type	Primary

End point timeframe:

Day 1 of Cycle 1 to Day 1 of Cycle 2 (1 cycle = 28 days) in dose-escalation phase

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No descriptive statistics were planned 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: No descriptive statistics were planned for this endpoint.

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: percentage of participants				
number (not applicable)	0.0	50.0	0.0	0.0

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	5	10	
Units: percentage of participants				
number (not applicable)	0.0	0.0	0.0	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Adverse Events (AEs)

End point title	Percentage of Participants with Adverse Events (AEs)[3]

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. Percentages have been rounded off to the first decimal point. The safety-evaluable population included all participants who received at least one dose of any component of the combination.

End point type	Primary

End point timeframe:

From study start up to end of study (Up to a maximum of 69 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No descriptive statistics were planned for this endpoint.

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: percentage of participants				
number (not applicable)	100.0	100.0	100.0	100.0

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	10	40
Units: percentage of participants				
number (not applicable)	100.0	100.0	100.0	100.0

End point values	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: percentage of participants				
number (not applicable)	97.4			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Complete Response (CR) at End of Induction (EOI), Determined by an Independent Review Committee (IRC) on the Basis of Positron Emission Tomography (PET) and Computed Tomography (CT) Scans

End point title	Percentage of Participants with Complete Response (CR) at End of Induction (EOI), Determined by an Independent Review Committee (IRC) on the Basis of Positron Emission Tomography (PET) and Computed Tomography (CT) Scans[4][5]

End point description:

CR at EOI was assessed by IRC according to Modified Lugano Response Criteria. Per MLRC CR based on PET-CT was defined as complete metabolic response in lymph nodes & extralymphatic sites with score of 1, 2, 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 &/or new lesions no evidence of fluorodeoxyglucose (FDG)-avid disease in bone marrow. Bone marrow is normal by morphology; if indeterminate,

immunohistochemistry negative. Efficacy-evaluable population included all participants who received at least one dose of any component of combination. Participants with FL & DLBCL who received polatuzumab vedotin &/or lenalidomide at RP2D (1.4 mg Pola + 20 mg L for FL; 20 mg L for DLBCL) in dose-escalation phase were also analyzed in addition to expansion phase participants.

End point type	Primary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.
[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	10	40	39
Units: percentage of participants				
number (confidence interval 90%)	66.7 (27.13 to 93.72)	0.0 (0.0 to 25.89)	60.0 (45.78 to 73.06)	38.5 (25.41 to 52.89)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR at EOI, Determined by the Investigator on the Basis of PET-CT Scans

End point title	Percentage of Participants with CR at EOI, Determined by the Investigator on the Basis of PET-CT Scans[6]

End point description:

CR at EOI was assessed by investigator according to Modified Lugano Response Criteria. Per MLRC CR based on PET-CT was = complete metabolic response in lymph nodes & extralymphatic sites with score of 1, 2, 3 with or without residual mass, on 5-point scale where 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 fluorodeoxyglucose (FDG)-avid disease in bone marrow. Bone marrow is normal by morphology; if indeterminate, immunohistochemistry negative. Percentages have been rounded off to the first decimal point. Efficacy-evaluable population=all participants who received at least one dose of any component of combination. Participants with FL & DLBCL who received polatuzumab vedotin &/or lenalidomide at RP2D (1.4 mg Pola + 20 mg L for FL; 20 mg L for DLBCL) in dose-escalation phase were also analyzed in addition to expansion phase participants.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	10	40	39
Units: percentage of participants				
number (confidence interval 90%)	66.7 (27.13 to 93.72)	0.0 (0.0 to 25.89)	60.0 (45.78 to 73.06)	33.3 (20.97 to 47.69)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR at EOI, Determined by the IRC on the Basis of CT Scans Alone

End point title	Percentage of Participants with CR at EOI, Determined by the IRC on the Basis of CT Scans Alone[7]

End point description:

CR at EOI was determined by IRC 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 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. Analysis was done 6-8 weeks after Cycle 6, Day 1 (cycle=28 days). Percentages have been rounded off to the first decimal point. Efficacy-evaluable population included all participants who received at least one dose of any component of the combination. Participants with FL and DLBCL who received polatuzumab vedotin and/or lenalidomide at RP2D (1.4 mg Pola + 20 mg L for FL; 20 mg L for DLBCL) in dose-escalation phase were also analyzed in addition to expansion phase participants. Number of Subjects Analyzed=number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	35	32
Units: percentage of participants				
number (confidence interval 90%)	16.7 (0.85 to 58.18)	0.0 (0.0 to 31.23)	31.4 (18.73 to 46.61)	12.5 (4.38 to 26.36)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR at EOI, Determined by Investigator on the Basis of CT Scans Alone

End point title	Percentage of Participants with CR at EOI, Determined by Investigator on the Basis of CT Scans Alone[8]

End point description:

CR at EOI was determined by Investigator 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 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. Analysis was done 6-8 weeks after Cycle 6, Day 1 (cycle=28 days). Percentages have been rounded off up to the second decimal point. Efficacy-evaluable population included all participants who received at least one dose of any component of the combination. Participants with FL and DLBCL who received polatuzumab vedotin and/or lenalidomide at RP2D (1.4 mg Pola + 20 mg L for FL; 20 mg L for DLBCL) in dose-escalation phase were also analyzed in addition to expansion phase participants. Number of Subjects Analyzed=number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks)

Notes:

[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: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	37	32
Units: percentage of participants				
number (confidence interval 90%)	16.7 (0.85 to 58.18)	0.0 (0.0 to 28.31)	29.7 (17.65 to 44.38)	28.1 (15.53 to 43.94)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response (OR) at EOI, Determined by the IRC on the Basis of PET-CT Scans

End point title	Percentage of Participants with Objective Response (OR) at EOI, Determined by the IRC on the Basis of PET-CT Scans[9]

End point description:

OR was defined as %of participants withCR/PR as assessed by IRC according toMLRC. Per MLRC CR based on PET-CT is complete MR in lymph nodes&ELS with score=1/2/3 with or without residual mass on 5PSwhere 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 new lesions&no evidence of FDG-avid disease in bone marrow.Bone marrow is normal by morphology; if indeterminate IHC negative. PR based on PET-CT=partial MR in lymph nodes&ELS with score=4/5 with reduced uptake compared with baseline&residual masses of any size at interim,residual uptake > uptake in normal bone marrow but reduced compared with baseline. Efficacy-evaluable population=all participants who received at least one dose of any component of combination. Participants with FL & DLBCL who received pola &/or L at RP2D in dose-escalation phase were also analyzed in addition to

expansion phase participants.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks)

Notes:

[9] - 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: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	10	40	39
Units: percentage of participants				
number (confidence interval 90%)	100.0 (60.70 to 100.0)	10.0 (0.51 to 39.42)	72.50 (58.61 to 83.75)	46.20 (32.35 to 60.42)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response at EOI, Determined by Investigator on the Basis of PET-CT Scans

End point title	Percentage of Participants with Objective Response at EOI, Determined by Investigator on the Basis of PET-CT Scans[10]

End point description:

OR=%of participants withCR/PR as assessed by investigator according toMLRC. Per MLRC CR based on PET-CT is complete MR in lymph nodes&ELS with score=1/2/3 with or without residual mass on 5PSwhere 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 new lesions&no evidence of FDG-avid disease in bone marrow.Bone marrow is normal by morphology; if indeterminate IHC negative. PR based on PET-CT=partial MR in lymph nodes&ELS with score=4/5 with reduced uptake compared with baseline&residual masses of any size at interim,residual uptake > uptake in normal bone marrow but reduced compared with baseline. Efficacy-evaluable population=all participants who received at least one dose of any component of combination. Participants with FL & DLBCL who received pola &/or L at RP2D in dose-escalation phase were also analyzed in addition to expansion phase participants.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (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: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	10	40	39
Units: percentage of participants				
number (confidence interval 90%)	100.0 (60.70 to 100.0)	10.0 (0.51 to 39.42)	80.0 (66.80 to 89.64)	46.20 (32.35 to 60.42)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response at EOI, Determined by the IRC on the Basis of CT Scans Alone

End point title	Percentage of Participants with Objective Response at EOI, Determined by the IRC on the Basis of CT Scans Alone[11]

End point description:

OR=% of participants with CR or PR as assessed by IRC based on MLRC. Per MLRC CR based on CT=complete radiologic response in lymph nodes & ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi & 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 lymph nodes & ELS with ≥50% decrease in SPD of up to 6 target measurable lymph nodes & 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. Percentages have been rounded off to the first decimal point. Efficacy-evaluable population=all participants who received at least one dose of any component of the combination. Participants with FL & DLBCL who received polatuzumab vedotin &/or lenalidomide at RP2D(1.4mg Pola+20 mg L for FL; 20mg L for DLBCL) in dose-escalation phase+expansion phase participants.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	35	32
Units: percentage of participants				
number (confidence interval 90%)	100.0 (60.70 to 100.0)	12.5 (0.64 to 47.07)	91.4 (79.31 to 97.62)	53.1 (37.34 to 68.46)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response, Determined by the Investigator on the Basis of CT Scans Alone

End point title	Percentage of Participants with Objective Response, Determined by the Investigator on the Basis of CT Scans Alone[12]

End point description:

OR = %participants with CR/PR as assessed by investigator based on MLRC. Per MLRC CR based on CT = complete radiologic response in lymph nodes&ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi & 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 lymph nodes & ELS with ≥50% decrease in SPD of up to 6 target measurable lymph nodes & 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. Values have been rounded off to the nearest whole number. Efficacy-evaluable population=all participants who received at least one dose of any component of the combination. Participants with FL & DLBCL who received polatuzumab vedotin &/or lenalidomide at RP2D (1.4mg Pola+20 mg L for FL 20mg L for DLBCL) in dose-escalation phase+expansion phase participants.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	37	32
Units: percentage of participants				
number (confidence interval 90%)	100.0 (60.70 to 100.0)	11.1 (0.57 to 42.91)	89.2 (76.95 to 96.22)	59.4 (43.35 to 74.03)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Best Response of CR or PR, Determined by the Investigator on the Basis of CT Scans Alone

End point title	Percentage of Participants with Best Response of CR or PR, Determined by the Investigator on the Basis of CT Scans Alone[13]

End point description:

BOR=CR/PR per CT per MLRC. Per MLRC, CR based on CT = complete radiologic response in lymph nodes & ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi & 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 lymph nodes & ELS with ≥50% decrease in SPD of up to 6 target measurable lymph nodes & 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. Efficacy-evaluable population=all participants who received at least one dose of any component of the combination. Participants with FL & DLBCL who received polatuzumab vedotin &/or lenalidomide at RP2D (1.4 mg Pola + 20 mg L for FL; 20 mg L for DLBCL) in dose-escalation phase were also analyzed in addition to expansion phase participants.

End point type	Secondary

End point timeframe:

Up to every 6 months until disease progression, unacceptable toxicity or study completion (up to approximately 69 months)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for Expansion Phase arms and Dose-escalation phase arms that received polatuzumab vedotin and/or lenalidomide at RP2D. Hence, only these arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	10	40	39
Units: percentage of participants				
number (confidence interval 90%)	100.0 (60.70 to 100.0)	50.0 (22.24 to 77.76)	90.0 (78.56 to 96.51)	79.5 (66.02 to 89.36)

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Obinutuzumab Concentration

End point title	Observed Serum Obinutuzumab Concentration[14]

End point description:

The pharmacokinetic (PK)-evaluable population included all participants who received at least one dose of any component of the combination and who provided at least one suitable postdose PK sample. 1 cycle = 28 days. 'Overall Number Analyzed' is the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint. Here, 9999= data is not evaluable as the samples were below lower limit of quantification (BLLQ); 99999= Since low number of participants were analysed, the geometric coefficient of variation was not calculated; 999999= participants were not analysed for this PK endpoint at the given timepoint; 9999999=Values were lower than reportable (LTR) for 1 participant. Since data was evaluable only for 1 participant geometric co-efficient of variation was not calculated.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1, 2, 4 & 6: predose & 30 mins postdose; EOI: predose;Day 1 of Maintenance Months 1,7, 13, 19; Day 120 post last dose; one year post last dose; study drug discontinuation; unscheduled visit: predose(up to approximately 69 months)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for those arms that received obinutuzumab. Hence, no other arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: micrograms per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Induction Cycle 1 Day 1 / Predose (n=3,4,2,6,37)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction Cycle 1 Day 1 / 30 mins(n=3,3,3,4,35)	394 (± 22.1)	358 (± 20.5)	351 (± 15.2)	333 (± 70.0)
Induction Cycle 2 Day 1 / Predose(n=3,3,3,4,36)	451 (± 23.5)	372 (± 37.0)	386 (± 4.6)	481 (± 23.1)
Induction Cycle 2 Day 1 / 30 mins(n=3,3,3,5,36)	830 (± 38.3)	749 (± 17.2)	695 (± 14.3)	667 (± 77.5)
Induction Cycle 4 Day 1 / Predose(n=3,2,2,4,34)	354 (± 15.0)	321 (± 43.6)	344 (± 13.4)	405 (± 24.9)
Induction Cycle 4 Day 1 / 30 mins(n=1,2,2,5,33)	103 (± 99999)	644 (± 42.8)	653 (± 20.6)	742 (± 27.8)
Induction Cycle 6 Day 1 / Predose(n=3,1,2,5,34)	255 (± 36.6)	504 (± 99999)	327 (± 5.8)	384 (± 52.2)
Induction Cycle 6 Day 1 / 30 mins(n=3,1,2,5,33)	730 (± 15.5)	804 (± 99999)	1.18 (± 9999999)	751 (± 35.3)
EOI / Predose(n=3,0,0,0,0)	108 (± 32.6)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Maintenance Month 1 / Predose(n=2,1,0,4,27)	231 (± 19.1)	381 (± 99999)	999999 (± 999999)	230 (± 87.4)
Maintenance Month 7 / Predose(n=1,1,1,3,21)	128 (± 99999)	212 (± 99999)	229 (± 99999)	125 (± 143.7)
Maintenance Month 13 / Predose(n=0,1,1,3,18)	999999 (± 999999)	142 (± 99999)	269 (± 99999)	134 (± 105.3)
Maintenance Month 19 / Predose(n=0,1,1,2,15)	999999 (± 999999)	354 (± 99999)	204 (± 99999)	154 (± 144.1)
Study Drug Discontinuation(n=0,1,0,1,10)	999999 (± 999999)	46.4 (± 99999)	999999 (± 999999)	17.3 (± 99999)
Day 120 Post Last Dose(n=1,0,0,0,7)	29.1 (± 99999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
1 Year Post Last Dose(n=0,0,1,0,7)	999999 (± 999999)	999999 (± 999999)	0.377 (± 99999)	999999 (± 999999)
Unscheduled / Predose(n=0,0,0,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

End point values	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: micrograms per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Induction Cycle 1 Day 1 / Predose (n=3,4,2,6,37)	9999 (± 9999)			

Induction Cycle 1 Day 1 / 30 mins(n=3,3,3,4,35)	182 (± 206.7)			
Induction Cycle 2 Day 1 / Predose(n=3,3,3,4,36)	312 (± 40.8)			
Induction Cycle 2 Day 1 / 30 mins(n=3,3,3,5,36)	588 (± 41.4)			
Induction Cycle 4 Day 1 / Predose(n=3,2,2,4,34)	270 (± 41.8)			
Induction Cycle 4 Day 1 / 30 mins(n=1,2,2,5,33)	547 (± 37.1)			
Induction Cycle 6 Day 1 / Predose(n=3,1,2,5,34)	255 (± 49.0)			
Induction Cycle 6 Day 1 / 30 mins(n=3,1,2,5,33)	543 (± 36.2)			
EOI / Predose(n=3,0,0,0,0)	999999 (± 999999)			
Maintenance Month 1 / Predose(n=2,1,0,4,27)	176 (± 60.1)			
Maintenance Month 7 / Predose(n=1,1,1,3,21)	135 (± 64.3)			
Maintenance Month 13 / Predose(n=0,1,1,3,18)	150 (± 70.7)			
Maintenance Month 19 / Predose(n=0,1,1,2,15)	165 (± 59.5)			
Study Drug Discontinuation(n=0,1,0,1,10)	87.5 (± 588.7)			
Day 120 Post Last Dose(n=1,0,0,0,7)	44.5 (± 806.5)			
1 Year Post Last Dose(n=0,0,1,0,7)	0.340 (± 955.9)			
Unscheduled / Predose(n=0,0,0,0,1)	561 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Rituximab Concentration

End point title	Observed Serum Rituximab Concentration[15]

End point description:

The PK-evaluable population included all participants who received at least one dose of any component of the combination and who provided at least one suitable PK samples. 'Overall Number Analyzed' is the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint. Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since low number of participants were analysed, the geometric coefficient of variation was not calculated.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1, 2, 4, 6: predose and 30 mins post-dose (1 cycle = 28 days) (up to approximately 69 months)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported only for those arms that received rituximab. Hence, no other arms have been included.

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	10	37
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Induction Cycle 1 Day 1 / Predose(n=2,5,10,36)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction Cycle 1 Day 1 / 30 mins(n=2,4,9,36)	151 (± 42.9)	203 (± 28.1)	175 (± 18.7)	174 (± 45.4)
Induction Cycle 2 Day 1 / Predose(n=3,3,7,34)	25.6 (± 78.0)	33.3 (± 43.7)	31.7 (± 26.2)	26.4 (± 73.4)
Induction Cycle 2 Day 1 / 30 mins(n=1,1,1,32)	133 (± 99999)	172 (± 99999)	222 (± 99999)	194 (± 36.4)
Induction Cycle 4 Day 1 / Predose(n=1,2,4,27)	20.4 (± 99999)	74.6 (± 33.8)	53.1 (± 43.7)	58.3 (± 44.4)
Induction Cycle 4 Day 1 / 30 mins(n=1,2,4,26)	159 (± 99999)	224 (± 5.7)	220 (± 16.2)	228 (± 36.6)
Induction Cycle 6 Day 1 / Predose(n=1,3,2,19)	15.3 (± 99999)	79.5 (± 42.3)	74.7 (± 22.1)	68.9 (± 60.6)
Induction Cycle 6 Day 1 / 30 mins(n=1,2,2,19)	135 (± 99999)	250 (± 7.6)	233 (± 1.8)	256 (± 26.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Polatuzumab Vedotin Analyte: Total Antibody

End point title	Serum Concentration of Polatuzumab Vedotin Analyte: Total Antibody

End point description:

The PK-evaluable population included all participants who received at least one dose of any component of the combination and who provided at least one suitable PK samples. 'Overall Number Analyzed' is the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint. C=cycle D=Day. Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since low number of participants were analysed, the geometric coefficient of variation was not calculated; 999999= participants were not analysed for this PK endpoint at the given timepoint. 9999999= Since more than one-third values were less than reportable, the geometric coefficient of variation was not calculated; 9999999=Values were LTR for 1 participant. Since data was evaluable only for 1 participant geometric co-efficient of variation was not calculated.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1, 2, 4: predose (1 cycle = 28 days), Day 120 post last dose; one year post last dose; study drug discontinuation; unscheduled visit: predose (up to approximately 69 months)

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1/ Predose(n=3,4,2,6,3,4,7,36,37)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C2D1/ Predose(n=3,3,3,6,3,3,7,37,35)	1.47 (± 16.2)	2.01 (± 51.1)	0.200 (± 958.3)	0.622 (± 152.8)
Induction C4D1/ Predose(n=3,2,2,5,1,3,4,35,26)	1.83 (± 51.7)	4.45 (± 20.5)	2.57 (± 30.5)	2.12 (± 69.0)
Study Drug Discontinuation(n=3,1,0,2,1,1,3,11,18)	0.106 (± 209.1)	0.170 (± 99999)	999999 (± 999999)	0.0903 (± 9999999)
Day 120 Post Last Dose(n=1,0,0,0,0,1,1,9,9)	0.0661 (± 99999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
1 Year Post Last Dose(n=1,0,1,0,0,0,0,7,9)	0.0250 (± 99999)	999999 (± 999999)	0.0250 (± 99999)	999999 (± 999999)
Unscheduled / Predose(n=0,0,0,0,0,0,0,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	37
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1/ Predose(n=3,4,2,6,3,4,7,36,37)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C2D1/ Predose(n=3,3,3,6,3,3,7,37,35)	1.57 (± 62.9)	1.61 (± 59.8)	1.47 (± 26.2)	0.339 (± 391.8)
Induction C4D1/ Predose(n=3,2,2,5,1,3,4,35,26)	0.900 (± 99999)	2.96 (± 44.4)	3.10 (± 43.6)	2.31 (± 48.5)
Study Drug Discontinuation(n=3,1,0,2,1,1,3,11,18)	1.50 (± 99999)	6.16 (± 99999)	3.25 (± 49.7)	0.175 (± 9999999)
Day 120 Post Last Dose(n=1,0,0,0,0,1,1,9,9)	999999 (± 999999)	0.208 (± 99999)	0.107 (± 99999)	0.0365 (± 9999999)
1 Year Post Last Dose(n=1,0,1,0,0,0,0,7,9)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	0.0357 (± 9999999)
Unscheduled / Predose(n=0,0,0,0,0,0,0,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

End point values	Expansion Phase: 1.8 mg Pola + 20 mg L			

	+ 375 mg R in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1/ Predose(n=3,4,2,6,3,4,7,36,37)	9999 (± 9999)			
Induction C2D1/ Predose(n=3,3,3,6,3,3,7,37,35)	1.35 (± 122.0)			
Induction C4D1/ Predose(n=3,2,2,5,1,3,4,35,26)	3.42 (± 46.1)			
Study Drug Discontinuation(n=3,1,0,2,1,1,3,11,18)	0.455 (± 448.4)			
Day 120 Post Last Dose(n=1,0,0,0,0,1,1,9,9)	0.0666 (± 9999999)			
1 Year Post Last Dose(n=1,0,1,0,0,0,0,7,9)	0.0250 (± 9999999)			
Unscheduled / Predose(n=0,0,0,0,0,0,0,0,1)	2.59 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of Polatuzumab Vedotin Analyte: Antibody-conjugated MMAE (acMMAE)

End point title	Plasma Concentration of Polatuzumab Vedotin Analyte: Antibody-conjugated MMAE (acMMAE)

End point description:

The PK-evaluable population included all participants who received at least one dose of any component of the combination and who provided at least one suitable PK samples. 'Overall Number Analyzed' is the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint. C=Cycle D=Day. Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since low number of participants were analysed, the geometric coefficient of variation was not calculated; 999999= participants were not analysed for this PK endpoint at the given timepoint; 9999999=Values were LTR for 1 participant. Since data was evaluable only for 1 participant geometric co-efficient of variation was not calculated.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1, 2, 4: predose and 30 mins post-dose; Days 8 and 15 of Cycle 1; Day 1 of Cycle 6: predose, study drug discontinuation; unscheduled visit: predose (1 cycle = 28 days) (up to approximately 69 months)

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: nanograms per milliliter (ng/mL)				

geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,6,3,5,10,38,38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C1D1 / 30 mins(n=2,4,3,6,3,5,10,34,36)	580 (± 41.6)	660 (± 24.7)	476 (± 16.0)	432 (± 27.9)
Induction C1D8 (n=3,3,3,5,3,5,7,35,36)	50.2 (± 7.3)	80.0 (± 17.6)	11.4 (± 232.2)	27.7 (± 69.2)
Induction C1D15 (n=3,3,3,5,2,5,7,33,33)	17.3 (± 5.5)	24.7 (± 13.8)	2.50 (± 483.1)	6.73 (± 118.8)
Induction C2D1 / Predose(n=3,3,3,6,3,3,7,38,33)	4.96 (± 21.3)	6.55 (± 58.7)	0.961 (± 477.5)	2.50 (± 119.8)
Induction C2D1 / 30 mins(n=3,3,3,6,3,3,7,36,31)	555 (± 15.8)	623 (± 18.4)	508 (± 22.7)	295 (± 174.6)
Induction C4D11 / Predose(n=3,1,2,5,1,3,4,36,26)	5.34 (± 73.9)	11.5 (± 99999)	8.47 (± 19.5)	7.68 (± 60.8)
Induction C4D1 / 30 mins(n=3,1,2,5,1,3,4,36,26)	32.9 (± 101980.7)	416 (± 87.7)	519 (± 9.3)	531 (± 17.6)
Induction C6D1 / Predose(n=3,1,2,5,1,3,2,33,21)	7.70 (± 26.0)	19.9 (± 99999)	9.37 (± 42.6)	9.70 (± 53.0)
Study Drug Discontinuation(n=2,1,0,1,0,0,0,4,0)	0.180 (± 9999999)	0.635 (± 99999)	999999 (± 999999)	0.180 (± 99999)
Unscheduled / Predose(n=0,0,0,0,0,0,0,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	10	40
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,6,3,5,10,38,38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C1D1 / 30 mins(n=2,4,3,6,3,5,10,34,36)	568 (± 27.7)	106 (± 60902.6)	513 (± 73.5)	333 (± 267.2)
Induction C1D8 (n=3,3,3,5,3,5,7,35,36)	58.9 (± 44.4)	52.0 (± 36.3)	43.9 (± 96.4)	11.9 (± 799.0)
Induction C1D15 (n=3,3,3,5,2,5,7,33,33)	22.3 (± 31.2)	18.3 (± 48.7)	18.6 (± 30.5)	5.95 (± 366.1)
Induction C2D1 / Predose(n=3,3,3,6,3,3,7,38,33)	7.44 (± 40.2)	5.58 (± 77.2)	6.12 (± 18.1)	1.88 (± 490.2)
Induction C2D1 / 30 mins(n=3,3,3,6,3,3,7,36,31)	537 (± 40.3)	568 (± 14.1)	716 (± 16.5)	481 (± 54.3)
Induction C4D11 / Predose(n=3,1,2,5,1,3,4,36,26)	4.19 (± 99999)	8.25 (± 59.4)	11.7 (± 74.2)	8.99 (± 36.7)
Induction C4D1 / 30 mins(n=3,1,2,5,1,3,4,36,26)	371 (± 99999)	507 (± 42.8)	737 (± 20.8)	492 (± 22.3)
Induction C6D1 / Predose(n=3,1,2,5,1,3,2,33,21)	3.06 (± 99999)	11.5 (± 41.6)	15.8 (± 45.4)	9.82 (± 40.4)
Study Drug Discontinuation(n=2,1,0,1,0,0,0,4,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	1.71 (± 378.4)
Unscheduled / Predose(n=0,0,0,0,0,0,0,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	23.1 (± 62.5)

End point values	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,6,3,5,10,38,38)	9999 (± 9999)			
Induction C1D1 / 30 mins(n=2,4,3,6,3,5,10,34,36)	522 (± 323.0)			
Induction C1D8 (n=3,3,3,5,3,5,7,35,36)	56.6 (± 90.2)			
Induction C1D15 (n=3,3,3,5,2,5,7,33,33)	16.9 (± 118.6)			
Induction C2D1 / Predose(n=3,3,3,6,3,3,7,38,33)	5.32 (± 103.6)			
Induction C2D1 / 30 mins(n=3,3,3,6,3,3,7,36,31)	451 (± 391.7)			
Induction C4D11 / Predose(n=3,1,2,5,1,3,4,36,26)	11.3 (± 45.2)			
Induction C4D1 / 30 mins(n=3,1,2,5,1,3,4,36,26)	645 (± 107.2)			
Induction C6D1 / Predose(n=3,1,2,5,1,3,2,33,21)	11.8 (± 66.0)			
Study Drug Discontinuation(n=2,1,0,1,0,0,0,4,0)	999999 (± 999999)			
Unscheduled / Predose(n=0,0,0,0,0,0,0,0,1)	9.78 (± 99999)			

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

End point description:

The PK-evaluable population included all participants who received at least one dose of any component of the combination and who provided at least one suitable PK samples. 'Overall Number Analyzed' is the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint. C=Cycle D=Day. Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since low number of participants were analysed, the geometric coefficient of variation was not calculated; 999999= participants were not analysed for this PK endpoint at the given timepoint. 9999999= Since more than one-third values were less than reportable, the geometric coefficient of variation was not calculated; 9999999=Values were LTR for 1 participant. Since data was evaluable only for 1 participant geometric co-efficient of variation was not calculated.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1, 2, 4: predose and 30 mins post-dose; Days 8 and 15 of Cycle 1 and Day 1 of Cycle 6: predose, study drug discontinuation; unscheduled visit: predose (1 cycle = 28 days) (up to approximately 69 months)

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,6,3,5,10,38,38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C1D1 / 30 mins(n=2,4,3,6,3,5,10,35,36)	0.228 (± 7.8)	0.160 (± 69.9)	0.420 (± 100.6)	0.233 (± 74.0)
Induction C1D8 (n=3,4,3,5,3,5,7,37,36)	1.15 (± 34.9)	2.05 (± 49.7)	2.40 (± 102.0)	1.64 (± 135.5)
Induction C1D15 (n=3,3,3,6,2,5,7,33,34)	0.457 (± 56.3)	0.459 (± 54.5)	0.387 (± 6.0)	0.435 (± 129.5)
Induction C2D1 / Predose(n=3,3,3,6,3,3,7,38,34)	0.0280 (± 9999999)	0.0315 (± 9999999)	0.0244 (± 9999999)	0.0334 (± 9999999)
Induction C2D1 / 30 minsn=3,3,3,6,3,3,7,36,31)	0.151 (± 68.6)	0.138 (± 133.0)	0.151 (± 49.8)	0.136 (± 339.9)
Induction C4D1 / Predose(n=3,1,2,5,1,3,4,36,26)	0.0431 (± 99999)	0.117 (± 99999)	0.0672 (± 56.9)	0.0283 (± 9999999)
Induction C4D1 / 30 mins(n=2,2,2,5,1,3,4,34,39)	0.0817 (± 9999999)	0.156 (± 18.7)	0.104 (± 7.1)	0.0752 (± 113.2)
Induction C6D1 / Predose(n=3,1,2,5,1,3,2,33,21)	0.0367 (± 68.3)	0.0929 (± 99999)	0.0821 (± 93.8)	0.0267 (± 9999999)
Study Drug Discontinuation(n=2,1,0,1,0,0,0,4,0)	0.0180 (± 9999999)	0.0180 (± 99999)	999999 (± 999999)	0.0180 (± 99999)
Unscheduled / Predose(n=0,0,0,0,0,0,0,1,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	10	40
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,6,3,5,10,38,38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C1D1 / 30 mins(n=2,4,3,6,3,5,10,35,36)	0.156 (± 62.1)	0.167 (± 214.8)	0.298 (± 198.7)	0.347 (± 327.5)
Induction C1D8 (n=3,4,3,5,3,5,7,37,36)	1.89 (± 76.1)	1.36 (± 29.6)	3.65 (± 75.3)	1.12 (± 227.0)

Induction C1D15 (n=3,3,3,6,2,5,7,33,34)	0.485 (± 204.0)	0.456 (± 39.8)	0.683 (± 63.3)	0.294 (± 170.9)
Induction C2D1 / Predose(n=3,3,3,6,3,3,7,38,34)	0.0501 (± 149.0)	0.0310 (± 9999999)	0.0527 (± 102.8)	0.0268 (± 9999999)
Induction C2D1 / 30 minsn=3,3,3,6,3,3,7,36,31)	0.186 (± 51.2)	0.123 (± 53.8)	0.157 (± 72.5)	0.102 (± 101.2)
Induction C4D1 / Predose(n=3,1,2,5,1,3,4,36,26)	0.0180 (± 99999)	0.0344 (± 61.0)	0.0729 (± 11.4)	0.0366 (± 9999999)
Induction C4D1 / 30 mins(n=2,2,2,5,1,3,4,34,39)	0.0180 (± 99999)	0.133 (± 50.9)	0.208 (± 44.9)	0.102 (± 57.7)
Induction C6D1 / Predose(n=3,1,2,5,1,3,2,33,21)	0.0180 (± 99999)	0.0517 (± 118.9)	0.0405 (± 9999999)	0.0342 (± 9999999)
Study Drug Discontinuation(n=2,1,0,1,0,0,0,4,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	0.0180 (± 9999999)
Unscheduled / Predose(n=0,0,0,0,0,0,0,1,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	0.180 (± 99999)

End point values	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,6,3,5,10,38,38)	9999 (± 9999)			
Induction C1D1 / 30 mins(n=2,4,3,6,3,5,10,35,36)	0.297 (± 111.1)			
Induction C1D8 (n=3,4,3,5,3,5,7,37,36)	2.56 (± 144.8)			
Induction C1D15 (n=3,3,3,6,2,5,7,33,34)	0.843 (± 125.2)			
Induction C2D1 / Predose(n=3,3,3,6,3,3,7,38,34)	0.0713 (± 125.0)			
Induction C2D1 / 30 minsn=3,3,3,6,3,3,7,36,31)	0.210 (± 77.3)			
Induction C4D1 / Predose(n=3,1,2,5,1,3,4,36,26)	0.0776 (± 101.5)			
Induction C4D1 / 30 mins(n=2,2,2,5,1,3,4,34,39)	0.213 (± 51.3)			
Induction C6D1 / Predose(n=3,1,2,5,1,3,2,33,21)	0.0852 (± 62.6)			
Study Drug Discontinuation(n=2,1,0,1,0,0,0,4,0)	999999 (± 999999)			
Unscheduled / Predose(n=0,0,0,0,0,0,0,1,1)	0.0180 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Lenalidomide Concentration

End point title	Observed Plasma Lenalidomide Concentration

End point description:

The PK-evaluable population included all participants who received at least one dose of any component of the combination and who provided at least one suitable PK samples. 'Overall Number Analyzed' is the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint. C=Cycle D=Day. Here, 9999= data is not evaluable as the samples were BLLQ; 99999= Since low number of participants were analysed, the geometric coefficient of variation was not calculated; 999999= participants were not analysed for this PK endpoint at the given timepoint; 9999999=Values were LTR for 1 participant. Since data was evaluable only for 1 participant geometric co-efficient of variation was not calculated.

End point type	Secondary

End point timeframe:

Day 1 Cycle 1: predose and 2 hours (hr) post-dose; Day 15 Cycle 1: predose, 0.5hr, 1hr, 2hr, 4hr, 8hr post-dose; Day 1 Cycle 6: 2hr post-dose; unscheduled visits: 2hr post-dose (1 cycle = 28 days) (up to approximately 69 months)

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,5,3,4,9,36,36)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C1D1 / 2h(n=3,4,3,5,3,4,10,37,36)	118 (± 44.0)	144 (± 30.3)	201 (± 54.0)	305 (± 37.1)
Induction C1D15 / Predose(n=3,3,2,6,2,4,7,32,31)	5.97 (± 628.0)	0.729 (± 540.0)	8.74 (± 277.0)	5.20 (± 275.1)
Induction C1D15 / 30 min(n=3,2,2,4,2,3,7,30,30)	64.0 (± 1553.1)	1.95 (± 9999999)	179 (± 220.1)	202 (± 115.6)
Induction C1D15 / 1h(n=3,3,2,5,2,3,7,33,30)	61.4 (± 1354.8)	40.8 (± 183.1)	189 (± 48.0)	272 (± 48.2)
Induction C1D15 / 2h(n=3,3,2,5,2,3,7,33,30)	117 (± 53.2)	93.3 (± 40.5)	202 (± 36.0)	200 (± 45.5)
Induction C1D15 / 4h(n=3,3,2,4,2,3,7,33,31)	96.4 (± 62.0)	65.7 (± 46.3)	116 (± 28.9)	152 (± 36.9)
Induction C1D15 / 8h(n=3,3,2,5,2,3,7,28,30)	35.0 (± 109.1)	29.2 (± 55.2)	56.8 (± 57.2)	49.8 (± 23.3)
Induction C6D1 / 2h(n=3,1,2,5,2,3,2,33,19)	124 (± 21.4)	76.1 (± 99999)	110 (± 35.1)	227 (± 48.1)
Unscheduled / 2h(n=0,0,0,0,0,0,0,3,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	10	37
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,5,3,4,9,36,36)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Induction C1D1 / 2h(n=3,4,3,5,3,4,10,37,36)	25.2 (± 239.4)	237 (± 47.4)	197 (± 184.1)	306 (± 43.1)
Induction C1D15 / Predose(n=3,3,2,6,2,4,7,32,31)	5.43 (± 9.1)	2.64 (± 68.0)	8.33 (± 112.0)	9.99 (± 260.9)
Induction C1D15 / 30 min(n=3,2,2,4,2,3,7,30,30)	12.5 (± 76.4)	41.7 (± 546.7)	73.3 (± 395.5)	124 (± 300.3)
Induction C1D15 / 1h(n=3,3,2,5,2,3,7,33,30)	69.9 (± 10.3)	224 (± 76.8)	187 (± 150.5)	236 (± 147.7)
Induction C1D15 / 2h(n=3,3,2,5,2,3,7,33,30)	118 (± 22.3)	232 (± 25.5)	328 (± 38.2)	305 (± 53.6)
Induction C1D15 / 4h(n=3,3,2,4,2,3,7,33,31)	79.9 (± 28.2)	134 (± 23.6)	245 (± 36.3)	214 (± 41.1)
Induction C1D15 / 8h(n=3,3,2,5,2,3,7,28,30)	44.0 (± 40.2)	57.0 (± 19.1)	105 (± 50.9)	103 (± 56.3)
Induction C6D1 / 2h(n=3,1,2,5,2,3,2,33,19)	36.2 (± 9999999)	258 (± 10.5)	255 (± 36.5)	237 (± 52.1)
Unscheduled / 2h(n=0,0,0,0,0,0,0,3,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	199 (± 53.3)

End point values	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Induction C1D1 / Predose(n=3,4,2,5,3,4,9,36,36)	9999 (± 9999)			
Induction C1D1 / 2h(n=3,4,3,5,3,4,10,37,36)	277 (± 60.0)			
Induction C1D15 / Predose(n=3,3,2,6,2,4,7,32,31)	10.4 (± 196.4)			
Induction C1D15 / 30 min(n=3,2,2,4,2,3,7,30,30)	94.5 (± 204.9)			
Induction C1D15 / 1h(n=3,3,2,5,2,3,7,33,30)	245 (± 106.8)			
Induction C1D15 / 2h(n=3,3,2,5,2,3,7,33,30)	242 (± 297.2)			
Induction C1D15 / 4h(n=3,3,2,4,2,3,7,33,31)	205 (± 45.4)			
Induction C1D15 / 8h(n=3,3,2,5,2,3,7,28,30)	103 (± 67.6)			
Induction C6D1 / 2h(n=3,1,2,5,2,3,2,33,19)	153 (± 515.5)			
Unscheduled / 2h(n=0,0,0,0,0,0,0,3,0)	999999 (± 999999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Human Anti-human Antibodies (HAHAs) to Obinutuzumab

End point title	Number of Participants with Human Anti-human Antibodies (HAHAs) to Obinutuzumab[16]

End point description:

The number of participants with positive results for HAHAs, also called anti-drug antibodies (ADAs) against obinutuzumab at baseline & at any of the post-baseline assessment time-points were reported. Number of participants positive for Treatment Emergent ADA = the number of post-baseline evaluable participants determined to have treatment induced ADA or treatment-enhanced ADA during study period. Treatment-induced ADA = negative or missing baseline ADA result & 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 titer unit (t.u.) > baseline titer result. Immunogenicity population included all safety-evaluable participants with at least one ADA Sample. 'Overall Number Analyzed'=number of participants with data available for analysis. 'Number Analyzed' =number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Baseline up to approximately 2 years after last dose (up to approximately 69 months)

Notes:

[16] - 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: Data is reported only for those arms that received obinutuzumab. Hence, no other arms have been included.

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	2	6
Units: participants				
Baseline prevalence of ADAs(n=3,4,2,6,38)	0	0	0	0
Post baseline incidence of ADAs(n=3,2,2,6,36)	0	0	0	0

End point values	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL			
Subject group type	Reporting group			
Number of subjects analysed	38			

Units: participants				
Baseline prevalence of ADAs(n=3,4,2,6,38)	3			
Post baseline incidence of ADAs(n=3,2,2,6,36)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Human Anti-chimeric Antibodies (HACAs) to Rituximab

End point title	Number of Participants with Human Anti-chimeric Antibodies (HACAs) to Rituximab[17]

End point description:

The number of participants with positive results for HACAs, also called ADAs against rituximab at baseline and at any of the post-baseline assessment time-points were reported. Number of participants positive for Treatment Emergent ADA = number of post-baseline evaluable participants determined to have treatment induced ADA or treatment-enhanced ADA during study period. Treatment-induced ADA = negative or missing baseline ADA result(s) & 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. > baseline titer result. Immunogenicity population included all safety-evaluable participants with at least one ADA Sample. 'Overall Number Analyzed' is the number of participants with data available for analysis. 'Number Analyzed' is the number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Baseline up to approximately 2 years after last dose (up to approximately 69 months)

Notes:

[17] - 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: Data is reported only for those arms that received rituximab. Hence, no other arms have been included.

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	10	37
Units: participants				
Baseline prevalence of ADAs(n=2,5,10,36)	0	0	0	0
Post baseline incidence of ADAs(n=3,4,7,37)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-therapeutic Antibodies (ATAs) to Polatuzumab Vedotin

End point title	Number of Participants with Anti-therapeutic Antibodies (ATAs) to Polatuzumab Vedotin

End point description:

The number of participants with positive results for ATAs, also called ADAs against polatuzumab vedotin at baseline & at any of the post-baseline assessment time-points were reported. Number of participants positive for Treatment Emergent ADA = the number of post-baseline evaluable participants determined to have treatment induced ADA 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 t.u. > baseline titer result. Immunogenicity population included all safety-evaluable participants with at least one ADA sample. 'Number Analyzed'=number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Baseline up to approx. 2 years after the last dose of polatuzumab vedotin (up to approximately 30 months)

End point values	Dose-escalation Phase: 1.4 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.8 mg Pola + 10 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 15 mg L + 1000 mg G in FL	Dose-escalation Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	6
Units: participants				
Baseline prevalence (n=3,4,2,6,3,5,10,38,37)	0	0	0	0
Post baseline incidence(n=3,4,3,6,3,4,7,38,37)	0	0	0	0

End point values	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL	Expansion Phase: 1.4 mg Pola + 20 mg L + 1000 mg G in FL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	10	39
Units: participants				
Baseline prevalence (n=3,4,2,6,3,5,10,38,37)	0	0	0	1
Post baseline incidence(n=3,4,3,6,3,4,7,38,37)	0	0	0	0

End point values	Expansion Phase: 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL			

Subject group type	Reporting group			
Number of subjects analysed	38			
Units: participants				
Baseline prevalence (n=3,4,2,6,3,5,10,38,37) Post baseline incidence(n=3,4,3,6,3,4,7,38,37)	1 0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline up to study completion/discontinuation (maximum of 69 months)

Adverse event reporting additional description:

The safety-evaluable population was defined as all participants who received at least one dose of any component of the combination.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Dose-escalation Phase: 1.4mg Pola + 10mg L + 1000mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 10 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 10mg L + 1000mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 10 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.8 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.4mg Pola + 15mg L + 1000mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 15 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.4mg Pola + 20mg L + 1000mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 10 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 milligrams per square meter (mg/m^2), as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 15 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Reporting group title	Expansion Phase: 1.4mg Pola + 20mg L + 1000mg G in FL

Reporting group description:

Participants with FL received lenalidomide, 20 mg capsules orally QD on Days 1-21 of Cycles 1 to 6 (1 cycle = 28 days) along with obinutuzumab, 1000 mg, as IV infusion on Days 1, 8, and 15 of Cycle 1 and then on Day 1 of Cycles 2-6, and polatuzumab vedotin, 1.4 mg/kg, IV infusion on Day 1 of Cycles 1-6, as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 12 months, and obinutuzumab, 1000 mg IV on Day 1 of every other month for up to 24 months.

Reporting group title	Expansion Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL

Reporting group description:

Participants with DLBCL received lenalidomide, 20 mg, capsules orally QD on Days 1-21 of Cycles 1-6 (1 cycle = 28 days) along with rituximab, 375 mg/m^2, as IV infusion on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, as an IV infusion on Day 1 of Cycles 1 to 6, as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 6 months. During consolidation treatment, participants received lenalidomide, 10 mg, capsules, orally, QD on Days 1-21 of each month (1 month = 28 days) for up to 6 months, and rituximab, 375 mg/m^2 IV on Day 1 of every other month for up to 6 months.

Serious adverse events	Dose-escalation Phase: 1.4mg Pola + 10mg L + 1000mg G in FL	Dose-escalation Phase: 1.8mg Pola + 10mg L + 1000mg G in FL	Dose-escalation Phase: 1.4mg Pola + 15mg L + 1000mg G in FL
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 4 (50.00%)	2 / 3 (66.67%)
number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PROSTATE CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 FLARE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
PYREXIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
HIP FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANKLE FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (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

THORACIC VERTEBRAL FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 LIMB FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
PERICARDITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
ENCEPHALOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 STEM STROKE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 STROKE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

VISION BLURRED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIP SWELLING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEVENS-JOHNSON SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 RETENTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
HYPOTHYROIDISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
BRONCHIOLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INJECTION SITE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ABSCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (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
EPIDIDYMITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
HYPERCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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	Dose-escalation	Dose-escalation	Dose-escalation

	Phase: 1.4mg Pola + 20mg L + 1000mg G in FL	Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	0 / 3 (0.00%)	4 / 10 (40.00%)
number of deaths (all causes)	2	3	10
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PROSTATE CANCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR FLARE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
HIP FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ANKLE FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THORACIC VERTEBRAL FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER LIMB FRACTURE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
PERICARDITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE CORONARY SYNDROME			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
ENCEPHALOPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN STEM STROKE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC STROKE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
NEUTROPENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
COLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIP SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEVENS-JOHNSON SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY RETENTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
HYPOTHYROIDISM			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
BRONCHIOLITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INJECTION SITE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ABSCESS			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPIDIDYMITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPERCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Expansion Phase: 1.4mg Pola + 20mg L + 1000mg G in FL	Expansion Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	26 / 40 (65.00%)	19 / 39 (48.72%)
number of deaths (all causes)	2	7	20
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PROSTATE CANCER			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR FLARE			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
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 NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
CANCER PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
DYSPNOEA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
HYPOXIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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			
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
HIP FRACTURE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANKLE FRACTURE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THORACIC VERTEBRAL FRACTURE			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 LIMB FRACTURE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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			
PERICARDITIS			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
ENCEPHALOPATHY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRAIN STEM STROKE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SEIZURE			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
ISCHAEMIC STROKE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood and lymphatic system disorders			
NEUTROPENIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 5 (0.00%)	4 / 40 (10.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	2 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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			
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIP SWELLING			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
RASH			

subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEVENS-JOHNSON SYNDROME			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
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 and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY RETENTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
HYPOTHYROIDISM			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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			
BRONCHIOLITIS			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
INJECTION SITE INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ABSCESS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 5 (0.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
UROSEPSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 5 (0.00%)	4 / 40 (10.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
SEPTIC SHOCK			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
EPIDIDYMITIS			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPERCALCAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (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 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (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

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

Non-serious adverse events	Dose-escalation Phase: 1.4mg Pola + 10mg L + 1000mg G in FL	Dose-escalation Phase: 1.8mg Pola + 10mg L + 1000mg G in FL	Dose-escalation Phase: 1.4mg Pola + 15mg L + 1000mg G in FL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR FLARE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

PYREXIA			
subjects affected / exposed	2 / 3 (66.67%)	0 / 4 (0.00%)	2 / 3 (66.67%)
occurrences (all)	3	0	6
PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
FATIGUE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	2 / 3 (66.67%)
occurrences (all)	2	0	2
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
FEELING ABNORMAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
PLEURAL EFFUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
EPISTAXIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
COUGH			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
INSOMNIA			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Investigations			
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
BLOOD LACTATE DEHYDROGENASE DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CREATININE RENAL CLEARANCE DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
CREATININE RENAL CLEARANCE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
WEIGHT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1

GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CARDIAC STRESS TEST ABNORMAL			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
IMMUNOGLOBULINS DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
AMYLASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
MUSCLE STRAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
FALL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CONTUSION			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
NEURALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BURNING SENSATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RESTING TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
SYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
PERIPHERAL MOTOR NEUROPATHY			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
DIZZINESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HEAD TITUBATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NEUTROPHILIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	1 / 3 (33.33%)
occurrences (all)	2	9	8
ANAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	3
LEUKOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TYMPANIC MEMBRANE PERFORATION			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
DRY EYE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MELAENA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
FLATULENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
ASCITES			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
UMBILICAL HERNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	2 / 3 (66.67%)
occurrences (all)	3	2	3
DENTAL CARIES			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	2 / 3 (66.67%)
occurrences (all)	2	2	2
ABDOMINAL PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
ODYNOPHAGIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
DYSPEPSIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
OCULAR ICTERUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	3	1	1
SKIN ULCER			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
PETECHIAE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
DIABETES INSIPIDUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOTHYROIDISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

MUSCLE SPASMS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TENDONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
DIASTASIS RECTI ABDOMINIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ARTHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SACRAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
ARTHRALGIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
MYALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
SINUSITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TONSILLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
NASOPHARYNGITIS			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
CONJUNCTIVITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
GASTROENTERITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
RHINITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GOUT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			

subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	3
DECREASED APPETITE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
HYPOCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
HYPOPROTEINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSLIPIDAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
HYPERURICAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Non-serious adverse events	Dose-escalation Phase: 1.4mg Pola + 20mg L + 1000mg G in FL	Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL	Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	3 / 3 (100.00%)	9 / 10 (90.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR FLARE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
HYPERTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	3	1	2
PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
FATIGUE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	2 / 10 (20.00%)
occurrences (all)	1	1	2
FEELING ABNORMAL			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
VULVOVAGINAL DRYNESS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
EPISTAXIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	3 / 6 (50.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	7	0	1
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Investigations			
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
BLOOD LACTATE DEHYDROGENASE DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
CREATININE RENAL CLEARANCE DECREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	2
CREATININE RENAL CLEARANCE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	1	0	2
CARDIAC STRESS TEST ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE			

INCREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	1	0	2
LIPASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
IMMUNOGLOBULINS DECREASED			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	2 / 10 (20.00%)
occurrences (all)	0	1	2
AMYLASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
MUSCLE STRAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
FALL			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
CONTUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR DYSFUNCTION			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
BURNING SENSATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
RESTING TREMOR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
DYSGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
SYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
HEAD TITUBATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	1	0	2
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
NEUTROPHILIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
NEUTROPENIA			
subjects affected / exposed	6 / 6 (100.00%)	2 / 3 (66.67%)	7 / 10 (70.00%)
occurrences (all)	18	7	15
ANAEMIA			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	5 / 10 (50.00%)
occurrences (all)	5	1	5
THROMBOCYTOPENIA			
subjects affected / exposed	5 / 6 (83.33%)	1 / 3 (33.33%)	2 / 10 (20.00%)
occurrences (all)	10	4	2
LEUKOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
TYMPANIC MEMBRANE PERFORATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

DRY EYE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DYSPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
MELAENA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
VOMITING			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
FLATULENCE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
GASTRITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
DRY MOUTH			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
RECTAL HAEMORRHAGE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
UMBILICAL HERNIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
HAEMORRHOIDAL HAEMORRHAGE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	2 / 10 (20.00%)
occurrences (all)	1	1	4
DENTAL CARIES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
ODYNOPHAGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			

OCULAR ICTERUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
HYPERHIDROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	4 / 10 (40.00%)
occurrences (all)	0	0	5
SKIN ULCER			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
DRY SKIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
PETECHIAE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
DIABETES INSIPIDUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
HYPOTHYROIDISM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
MUSCLE SPASMS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
TENDONITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
NECK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
DIASTASIS RECTI ABDOMINIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ARTHRITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
SACRAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ARTHRALGIA			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
MYALGIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	3 / 10 (30.00%)
occurrences (all)	0	0	3
Infections and infestations			
SINUSITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
BRONCHITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
HERPES ZOSTER			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
TONSILLITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
INFLUENZA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
CONJUNCTIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	4	0	1
PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
GOUT			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
HYPOKALAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	3	0	2
DECREASED APPETITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
HYPONATRAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
HYPOPROTEINAEMIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
DYSLIPIDAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL	Expansion Phase: 1.4mg Pola + 20mg L + 1000mg G in FL	Expansion Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	40 / 40 (100.00%)	37 / 39 (94.87%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR FLARE			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
SQUAMOUS CELL CARCINOMA			

subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	2 / 39 (5.13%)
occurrences (all)	0	5	2
PYREXIA			
subjects affected / exposed	1 / 5 (20.00%)	13 / 40 (32.50%)	5 / 39 (12.82%)
occurrences (all)	1	17	5
PAIN			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
FATIGUE			
subjects affected / exposed	1 / 5 (20.00%)	11 / 40 (27.50%)	6 / 39 (15.38%)
occurrences (all)	1	11	6
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 5 (20.00%)	4 / 40 (10.00%)	0 / 39 (0.00%)
occurrences (all)	1	4	0
ASTHENIA			
subjects affected / exposed	0 / 5 (0.00%)	7 / 40 (17.50%)	6 / 39 (15.38%)
occurrences (all)	0	12	6
FEELING ABNORMAL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			

subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 5 (0.00%)	4 / 40 (10.00%)	2 / 39 (5.13%)
occurrences (all)	0	4	2
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	3 / 39 (7.69%)
occurrences (all)	0	1	4
Immune system disorders			
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Reproductive system and breast disorders			
VULVOVAGINAL DRYNESS			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 5 (20.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	1	2	2
RHINORRHOEA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
PLEURAL EFFUSION			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
DYSPNOEA			
subjects affected / exposed	1 / 5 (20.00%)	5 / 40 (12.50%)	1 / 39 (2.56%)
occurrences (all)	2	5	1
EPISTAXIS			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	0	12	0
OROPHARYNGEAL PAIN			

subjects affected / exposed	0 / 5 (0.00%)	4 / 40 (10.00%)	1 / 39 (2.56%)
occurrences (all)	0	4	1
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	1 / 5 (20.00%)	10 / 40 (25.00%)	5 / 39 (12.82%)
occurrences (all)	1	11	5
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
INSOMNIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Investigations			
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	4 / 40 (10.00%)	2 / 39 (5.13%)
occurrences (all)	3	5	2
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	5 / 40 (12.50%)	3 / 39 (7.69%)
occurrences (all)	1	10	4
BLOOD LACTATE DEHYDROGENASE DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
CREATININE RENAL CLEARANCE DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	5 / 40 (12.50%)	4 / 39 (10.26%)
occurrences (all)	4	7	8

CREATININE RENAL CLEARANCE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	1	12	5
WEIGHT DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	1 / 39 (2.56%)
occurrences (all)	0	3	1
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 5 (40.00%)	8 / 40 (20.00%)	5 / 39 (12.82%)
occurrences (all)	5	11	8
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	5 / 40 (12.50%)	3 / 39 (7.69%)
occurrences (all)	2	10	4
CARDIAC STRESS TEST ABNORMAL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	4 / 40 (10.00%)	0 / 39 (0.00%)
occurrences (all)	1	6	0
LIPASE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
IMMUNOGLOBULINS DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
C-REACTIVE PROTEIN INCREASED			

subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	0	3	2
AMYLASE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
MUSCLE STRAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 5 (20.00%)	17 / 40 (42.50%)	2 / 39 (5.13%)
occurrences (all)	1	19	2
FALL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 5 (20.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
NEURALGIA			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	0	3	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
BURNING SENSATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
RESTING TREMOR			

subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	3	1
HEADACHE			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	2 / 39 (5.13%)
occurrences (all)	0	3	3
SYNCOPE			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
PARAESTHESIA			
subjects affected / exposed	0 / 5 (0.00%)	4 / 40 (10.00%)	1 / 39 (2.56%)
occurrences (all)	0	4	1
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
DIZZINESS			
subjects affected / exposed	0 / 5 (0.00%)	5 / 40 (12.50%)	3 / 39 (7.69%)
occurrences (all)	0	7	4
HEAD TITUBATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	3 / 39 (7.69%)
occurrences (all)	0	3	3
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	3	0
NEUTROPHILIA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	0	5	1
NEUTROPENIA			
subjects affected / exposed	3 / 5 (60.00%)	26 / 40 (65.00%)	25 / 39 (64.10%)
occurrences (all)	7	117	62

ANAEMIA			
subjects affected / exposed	2 / 5 (40.00%)	18 / 40 (45.00%)	14 / 39 (35.90%)
occurrences (all)	3	29	22
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 5 (20.00%)	22 / 40 (55.00%)	10 / 39 (25.64%)
occurrences (all)	6	50	18
LEUKOPENIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	4	1
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
TYMPANIC MEMBRANE PERFORATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
VISION BLURRED			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	3	0
DRY EYE			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
DYSPHAGIA			
subjects affected / exposed	1 / 5 (20.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2

MELAENA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
CONSTIPATION			
subjects affected / exposed	2 / 5 (40.00%)	7 / 40 (17.50%)	8 / 39 (20.51%)
occurrences (all)	2	10	8
VOMITING			
subjects affected / exposed	0 / 5 (0.00%)	5 / 40 (12.50%)	4 / 39 (10.26%)
occurrences (all)	0	5	4
FLATULENCE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
DRY MOUTH			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
UMBILICAL HERNIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 5 (20.00%)	4 / 40 (10.00%)	3 / 39 (7.69%)
occurrences (all)	2	5	3
TOOTHACHE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	2
HAEMORRHOIDAL HAEMORRHAGE			
subjects affected / exposed	1 / 5 (20.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0

DIARRHOEA			
subjects affected / exposed	1 / 5 (20.00%)	17 / 40 (42.50%)	13 / 39 (33.33%)
occurrences (all)	1	24	23
DENTAL CARIES			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	0 / 5 (0.00%)	8 / 40 (20.00%)	5 / 39 (12.82%)
occurrences (all)	0	10	5
ABDOMINAL PAIN			
subjects affected / exposed	1 / 5 (20.00%)	6 / 40 (15.00%)	3 / 39 (7.69%)
occurrences (all)	1	6	3
ODYNOPHAGIA			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	1 / 39 (2.56%)
occurrences (all)	0	3	1
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
DYSPEPSIA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hepatobiliary disorders			
OCULAR ICTERUS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
DYSHIDROTIC ECZEMA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	3 / 39 (7.69%)
occurrences (all)	0	0	3
RASH			
subjects affected / exposed	0 / 5 (0.00%)	5 / 40 (12.50%)	7 / 39 (17.95%)
occurrences (all)	0	5	10
SKIN ULCER			

subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	0	2	2
PRURITUS			
subjects affected / exposed	1 / 5 (20.00%)	4 / 40 (10.00%)	2 / 39 (5.13%)
occurrences (all)	1	4	3
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	3 / 39 (7.69%)
occurrences (all)	0	3	4
SKIN EXFOLIATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
DRY SKIN			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
NIGHT SWEATS			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	0	4	0
PETECHIAE			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
URTICARIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
HAEMATURIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
DYSURIA			
subjects affected / exposed	1 / 5 (20.00%)	3 / 40 (7.50%)	2 / 39 (5.13%)
occurrences (all)	1	4	2

RENAL FAILURE			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Endocrine disorders			
DIABETES INSIPIDUS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
HYPOTHYROIDISM			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
MUSCLE SPASMS			
subjects affected / exposed	1 / 5 (20.00%)	5 / 40 (12.50%)	1 / 39 (2.56%)
occurrences (all)	1	7	1
TENDONITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
BACK PAIN			
subjects affected / exposed	0 / 5 (0.00%)	5 / 40 (12.50%)	6 / 39 (15.38%)
occurrences (all)	0	5	7
DIASTASIS RECTI ABDOMINIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	0	1	3
ARTHRITIS			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	3	1
SACRAL PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
ARTHRALGIA			

subjects affected / exposed	0 / 5 (0.00%)	7 / 40 (17.50%)	2 / 39 (5.13%)
occurrences (all)	0	9	2
MYALGIA			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	0	4	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	0	2	2
Infections and infestations			
SINUSITIS			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	0	5	0
BRONCHITIS			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	0	4	0
HERPES ZOSTER			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	2 / 39 (5.13%)
occurrences (all)	0	3	2
TONSILLITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 5 (20.00%)	8 / 40 (20.00%)	2 / 39 (5.13%)
occurrences (all)	1	11	2
CONJUNCTIVITIS			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 5 (20.00%)	6 / 40 (15.00%)	2 / 39 (5.13%)
occurrences (all)	2	9	2
PNEUMONIA			
subjects affected / exposed	0 / 5 (0.00%)	4 / 40 (10.00%)	0 / 39 (0.00%)
occurrences (all)	0	6	0
GASTROENTERITIS			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
RHINITIS			
subjects affected / exposed	0 / 5 (0.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	0	3	0
ORAL HERPES			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	7 / 40 (17.50%)	3 / 39 (7.69%)
occurrences (all)	0	13	3
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION BACTERIAL			
subjects affected / exposed	1 / 5 (20.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	4 / 39 (10.26%)
occurrences (all)	0	5	4
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	4 / 39 (10.26%)
occurrences (all)	0	2	4
GOUT			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	4 / 39 (10.26%)
occurrences (all)	0	6	5
DECREASED APPETITE			
subjects affected / exposed	0 / 5 (0.00%)	8 / 40 (20.00%)	6 / 39 (15.38%)
occurrences (all)	0	8	6
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	4 / 39 (10.26%)
occurrences (all)	0	1	7
HYPONATRAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
HYPERPHOSPHATAEMIA			
subjects affected / exposed	1 / 5 (20.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	2	2	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
DEHYDRATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 5 (20.00%)	5 / 40 (12.50%)	5 / 39 (12.82%)
occurrences (all)	5	13	9
HYPOPROTEINAEMIA			

subjects affected / exposed	0 / 5 (0.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	0	2	2
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
DYSLIPIDAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 July 2017	The study design was updated to include a dose-escalation phase in R/R DLBCL participants. The collection of human anti-chimeric antibodies in relation to rituximab was added as an immunogenicity objective. Eligibility criteria were added to exclude participants with suspected active or latent tuberculosis. Enrollment rules into the dose-escalation phase have been updated for participants' safety considerations. Few clarifications have been added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported