



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 | v2 (current) |
| This version publication date | 09 April 2024 |
| First version publication date | 18 December 2022 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Align results data set with updates made to CT.gov results post NIH QA comments. |

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/m²), 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/m² 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/m² 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/m² 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/m², 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/m² 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/m² 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/m² 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/m², 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/m² 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/m² 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/m² 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/m², 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/m² 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/m² 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/m² 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 | - |
|-------------------|---|---|---|

Baseline characteristics

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/m²), 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/m² 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/m², 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/m² 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/m², 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/m² 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/m², 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/m² 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 standard deviation | 61.4 ± 14.2 | 61.6 ± 11.2 | 68.4 ± 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

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/m²), 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/m² 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/m², 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/m² 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/m², 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/m² 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/m², 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/m² 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=dose expansion participants who received atleast 1 dose of any component of the combination. As pre-specified in the protocol, data was collected and analysed only for participants in expansion phase arms & those participants in dose-escalation arms who received study drugs at RP2D (i.e. arms: 1.4 mg Pola + 20 mg L+1000G for FL; 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL)

| | |
|----------------|---------|
| 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

[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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

| 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=dose expansion participants who received atleast 1 dose of any component of the combination. As pre-specified in the protocol, data was collected and analysed only for participants in expansion phase arms & those participants in dose-escalation arms who received study drugs at RP2D.

| | |
|----------------|-----------|
| 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

| 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=dose expansion participants who received atleast 1 dose of any component of the combination. As pre-specified in the protocol, data was collected and analysed only for participants in expansion phase arms & those participants in dose-escalation arms who received study drugs at RP2D. (1.4 mg Pola + 20 mg L for FL; 20 mg L for DLBCL) . Number of Subjects Analyzed=number

| | |
|----------------|-----------|
| 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

| 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

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=dose expansion participants who received at least 1 dose of any component of the combination. As pre-specified in the protocol, data was collected and analysed only for participants in expansion phase arms & those participants in dose-escalation arms who received study drugs at RP2D. 1.4 mg Pola + 20 mg L for FL; 20 mg L for DLBCL). Number of Subjects Analyzed=number of subject 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

| 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 with CR/PR as assessed by IRC according to MLRC. 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 5PS where 1=no uptake above background 2=uptake \leq mediastinum 3=uptake > mediastinum but \leq 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D..

| 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. As pre-specified in the protocol, data was collected and analysed only for participants in expansion arms & n dose-escalation arms who received drugs at RP2D.

| | |
|--|-----------|
| 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

| 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 \leq 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 \geq 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 \geq 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. As pre-specified in the protocol, data was collected and analysed only for participants in expansion phase arms & those participants in dose-escalation arms who received study drugs atRP2D

| | |
|----------------|-----------|
| 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D..

| 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 $\geq 50\%$ 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 $\geq 50\%$ 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. As pre-specified in the protocol, data was collected & analysed only for participants in expansion phase arms & those participants in dose-escalation arms who received study drugs at RP2D.

| | |
|----------------|-----------|
| 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

| 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 $\geq 50\%$ 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 $\geq 50\%$ 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. As pre-specified in the protocol, data was collected and analysed only for participants in expansion phase arms & those participants in dose-escalation arms who received study drugs at RP2D (i.e. arms: 1.4 mg Pola + 20 mg L+1000G for FL; 1.8 mg Pola + 20 mg L + 375 mg R in DLBCL).

| | |
|----------------|-----------|
| 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: Endpoint is applicable only for dose escalation arms and dose expansion arms which received the study drugs at RP2D.

| 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 (BLQ); 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: Endpoint is applicable only for obinutuzumab arms.

| 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: Endpoint is applicable only for rituximab arms.

| 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; 99999999=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=2,1,0,1,0,0,4,0) | 0.180 (± 9999999) | 0.635 (± 99999) | 999999 (± 999999) | 0.180 (± 99999) |
| Unscheduled / Predose(n=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=2,1,0,1,0,0,4,0) | 999999 (± 999999) | 999999 (± 999999) | 999999 (± 999999) | 1.71 (± 378.4) |
| Unscheduled / Predose(n=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; 99999999=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 mins(n=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=2,1,0,1,0,0,4,0) | 999999 (± 999999) | 999999 (± 999999) | 999999 (± 999999) | 0.0180 (± 9999999) |
| Unscheduled / Predose(n=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=2,1,0,1,0,0,4,0) | 999999 (± 999999) | | | |
| Unscheduled / Predose(n=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 (± 999999) | 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=0,0,0,0,0,0,3,0) | 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=0,0,0,0,0,0,3,0) | 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: Endpoint is applicable only for Obinutuzumab arms.

| 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: Endpoint is applicable only for rituximab arms.

| 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) | 1 | | | |
| Post baseline incidence(n=3,4,3,6,3,4,7,38,37) | 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: 1.8mg 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/m², 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/m² IV on Day 1 of every other month for up to 6 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/m²), 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/m² IV on Day 1 of every other month for up to 6 months.

| | |
|-----------------------|---|
| 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 + 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/m², 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/m² 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/m², 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/m² IV on Day 1 of every other month for up to 6 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.

| Serious adverse events | Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL | Dose-escalation Phase: 1.4mg Pola + 15mg L + 1000mg G in FL | Dose-escalation Phase: 1.4mg Pola + 20mg L + 1000mg G in FL |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 3 (66.67%) | 3 / 6 (50.00%) |
| number of deaths (all causes) | 2 | 1 | 2 |
| 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 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR FLARE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LUNG NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CANCER PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| PYREXIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| 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%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONITIS | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOXIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY EMBOLISM | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| HIP FRACTURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANKLE FRACTURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|----------------|----------------|
| THORACIC VERTEBRAL FRACTURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FALL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER LIMB FRACTURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FEMUR FRACTURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| PERICARDITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ACUTE MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ACUTE CORONARY SYNDROME | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIAC FAILURE | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| ENCEPHALOPATHY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRAIN STEM STROKE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEIZURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ISCHAEMIC STROKE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |

| | | | |
|---|---------------|---------------|---------------|
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| GASTRIC HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COLITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIP SWELLING | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| RASH | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STEVENSON-JOHNSON SYNDROME | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |

| | | | |
|---|---------------|---------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY RETENTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| HYPOTHYROIDISM | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| BRONCHIOLITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INJECTION SITE INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LOWER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LUNG ABSCESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|---------------|----------------|
| NEUTROPENIC SEPSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UROSEPSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 PNEUMONIA | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPTIC SHOCK | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPIDIDYMITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------|-----------------|-----------------|-----------------|
| Serious adverse events | Dose-escalation | Dose-escalation | Dose-escalation |
|-------------------------------|-----------------|-----------------|-----------------|

| | Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL | Phase: 1.4mg Pola + 10mg L + 1000mg G in FL | Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 3 (100.00%) | 4 / 10 (40.00%) |
| number of deaths (all causes) | 3 | 1 | 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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| INTERSTITIAL LUNG DISEASE | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 | 0 / 3 (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 |
| FALL | | | |
| subjects affected / exposed | 0 / 3 (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 LIMB FRACTURE | | | |
| subjects affected / exposed | 0 / 3 (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 |
| FEMUR FRACTURE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (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 |
| Cardiac disorders | | | |
| PERICARDITIS | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 | 0 / 3 (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 |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 3 (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 | 0 / 3 (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 |
| Eye disorders | | | |
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (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 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (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 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (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 |
| LIP SWELLING | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 | 0 / 3 (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 |
| Infections and infestations | | | |
| BRONCHIOLITIS | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (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 / 3 (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 | 0 / 3 (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 |
| NEUTROPENIC SEPSIS | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (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 / 3 (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 / 3 (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 | 0 / 3 (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 | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 / 3 (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 | 0 / 3 (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 LYSIS SYNDROME | | | |

| | | | |
|---|---------------|---------------|----------------|
| subjects affected / exposed | 0 / 3 (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 | Expansion Phase: 1.4mg Pola + 20mg L + 1000mg G in FL | Expansion Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL | Dose-escalation Phase: 1.8mg Pola + 10mg L + 1000mg G in FL |
|--|---|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 26 / 40 (65.00%) | 19 / 39 (48.72%) | 2 / 4 (50.00%) |
| number of deaths (all causes) | 7 | 20 | 2 |
| number of deaths resulting from adverse events | 1 | 1 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) PROSTATE CANCER | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR FLARE | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LUNG NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CANCER PAIN | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions PYREXIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 2 | 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 | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSпноEA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPoxIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY EMBOLISM | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Injury, poisoning and procedural complications | | | |
| HIP FRACTURE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANKLE FRACTURE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| THORACIC VERTEBRAL FRACTURE | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FALL | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER LIMB FRACTURE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FEMUR FRACTURE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| PERICARDITIS | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|---------------|
| ACUTE MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ACUTE CORONARY SYNDROME | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| ENCEPHALOPATHY | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRAIN STEM STROKE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| SEIZURE | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ISCHAEMIC STROKE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|----------------|---------------|
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 2 / 4 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| VISION BLURRED | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| GASTRIC HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COLITIS | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIP SWELLING | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| RASH | | | |

| | | | |
|---|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STEVENS-JOHNSON SYNDROME | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY RETENTION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| HYPOTHYROIDISM | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| BRONCHIOLITIS | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INJECTION SITE INFECTION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (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 |
| COVID-19 PNEUMONIA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| SEPTIC SHOCK | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPIDIDYMITIS | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |

| | | | |
|---|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (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 |

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

| Non-serious adverse events | Dose-escalation Phase: 1.8mg Pola + 15mg L + 375mg R in DLBCL | Dose-escalation Phase: 1.4mg Pola + 15mg L + 1000mg G in FL | Dose-escalation Phase: 1.4mg Pola + 20mg L + 1000mg G in FL |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 5 (100.00%) | 3 / 3 (100.00%) | 6 / 6 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| TUMOUR FLARE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SQUAMOUS CELL CARCINOMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| FLUSHING | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORTHOSTATIC HYPOTENSION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPERTENSION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| CHILLS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------|----------------|----------------|
| PYREXIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 3 (66.67%) | 3 / 6 (50.00%) |
| occurrences (all) | 1 | 6 | 3 |
| PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FATIGUE | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 3 (66.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 1 | 1 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| GAIT DISTURBANCE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PERIPHERAL SWELLING | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CYTOKINE RELEASE SYNDROME | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| VULVOVAGINAL DRYNESS subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| PRODUCTIVE COUGH subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| RHINORRHOEA subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 1 / 3 (33.33%) 1 | 1 / 6 (16.67%) 1 |
| PLEURAL EFFUSION subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| DYSPNOEA subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 2 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| EPISTAXIS subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| OROPHARYNGEAL PAIN subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| RHINITIS ALLERGIC subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| UPPER-AIRWAY COUGH SYNDROME subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| COUGH subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 1 / 3 (33.33%) 1 | 3 / 6 (50.00%) 7 |
| Psychiatric disorders | | | |
| DEPRESSION subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| INSOMNIA | | | |

| | | | |
|---------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Investigations | | | |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| BLOOD LACTATE DEHYDROGENASE DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CREATININE RENAL CLEARANCE DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 4 | 1 | 2 |
| CREATININE RENAL CLEARANCE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| BLOOD GLUCOSE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 5 | 1 | 2 |

| | | | |
|--|----------------|---------------|----------------|
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 2 | 0 | 1 |
| CARDIAC STRESS TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD ALKALINE PHOSPHATASE INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| LIPASE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| IMMUNOGLOBULINS DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| AMYLASE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| MUSCLE STRAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 1 | 0 | 3 |
| FALL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| CONTUSION | | | |

| | | | |
|--|--------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Cardiac disorders | | | |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| LEFT VENTRICULAR DYSFUNCTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| NEURALGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PERIPHERAL SENSORY NEUROPATHY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BURNING SENSATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RESTING TREMOR | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 2 | 1 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PARAESTHESIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| PERIPHERAL MOTOR NEUROPATHY | | | |

| | | | |
|--------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HEAD TITUBATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| NEUROPATHY PERIPHERAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood and lymphatic system disorders | | | |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUTROPHILIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 1 / 3 (33.33%) | 6 / 6 (100.00%) |
| occurrences (all) | 7 | 8 | 18 |
| ANAEMIA | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 3 (33.33%) | 3 / 6 (50.00%) |
| occurrences (all) | 3 | 2 | 5 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 5 / 6 (83.33%) |
| occurrences (all) | 6 | 3 | 10 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| TYMPANIC MEMBRANE PERFORATION | | | |

| | | | |
|--|--------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Eye disorders | | | |
| OCULAR HYPERAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DRY EYE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PERIORBITAL OEDEMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| DYSPHAGIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MELAENA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONSTIPATION | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 2 | 0 | 1 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| FLATULENCE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ASCITES | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| GASTRITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| DRY MOUTH | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UMBILICAL HERNIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HAEMORRHOIDAL HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 3 (66.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 3 | 1 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 3 (66.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ODYNOPHAGIA | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Hepatobiliary disorders | | | |
| OCULAR ICTERUS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| DYSHIDROTIC ECZEMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| SKIN ULCER | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH ERYTHEMATOUS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SKIN EXFOLIATION | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| DRY SKIN | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| NIGHT SWEATS | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 1 / 3 (33.33%) 1 | 1 / 6 (16.67%) 1 |
| PETECHIAE | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| URTICARIA | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 6 (0.00%) 0 |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| HAEMATURIA | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| DYSURIA | | | |
| subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| RENAL FAILURE | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Endocrine disorders | | | |
| DIABETES INSIPIDUS | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| HYPOTHYROIDISM | | | |
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| TENDONITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NECK PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DIASTASIS RECTI ABDOMINIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ARTHRITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SACRAL PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ARTHRALGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 2 / 6 (33.33%) |
| occurrences (all) | 0 | 1 | 3 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 1 | 1 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| SINUSITIS | | | |

| | | | |
|-----------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| BRONCHITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LOWER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HERPES ZOSTER | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TONSILLITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 2 | 1 | 4 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL CANDIDIASIS | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 1 | 1 |
| CYTOMEGALOVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| UPPER RESPIRATORY TRACT INFECTION BACTERIAL | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CANDIDA INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| GOUT | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPOKALAEMIA | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 3 | 3 |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERPHOSPHATAEMIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| VITAMIN D DEFICIENCY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| HYPOPROTEINAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSLIPIDAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 3 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERURICAEMIA | | | |

| | | | |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 3 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| Non-serious adverse events | Dose-escalation Phase: 1.8mg Pola + 10mg L + 375mg R in DLBCL | Dose-escalation Phase: 1.4mg Pola + 10mg L + 1000mg G in FL | Dose-escalation Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3 / 3 (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 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SQUAMOUS CELL CARCINOMA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| FLUSHING | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORTHOSTATIC HYPOTENSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTENSION | | | |
| subjects affected / exposed | 0 / 3 (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 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 2 / 3 (66.67%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 3 | 2 |
| PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| FATIGUE | | | |

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

| | | | |
|---------------------------------------|---------------|----------------|-----------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| EPISTAXIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINITIS ALLERGIC | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER-AIRWAY COUGH SYNDROME | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Psychiatric disorders | | | |
| DEPRESSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Investigations | | | |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD CREATININE INCREASED | | | |

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

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

| | | | |
|-------------------------------|---------------|----------------|-----------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| NEURALGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PERIPHERAL SENSORY NEUROPATHY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BURNING SENSATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RESTING TREMOR | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PARAESTHESIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PERIPHERAL MOTOR NEUROPATHY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| HEAD TITUBATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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

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

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| UMBILICAL HERNIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HAEMORRHOIDAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 2 / 3 (66.67%) | 2 / 10 (20.00%) |
| occurrences (all) | 1 | 3 | 4 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| ODYNOPHAGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatobiliary disorders | | | |

| | | | |
|---|--------------------|---------------------|----------------------|
| OCULAR ICTERUS subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| DYSHIDROTIC ECZEMA subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| HYPERHIDROSIS subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| RASH subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 2 / 3 (66.67%) 3 | 4 / 10 (40.00%) 5 |
| SKIN ULCER subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| RASH ERYTHEMATOUS subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| PRURITUS subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| RASH MACULO-PAPULAR subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| SKIN EXFOLIATION subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| DRY SKIN subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 10 (0.00%) 0 |
| NIGHT SWEATS subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| PETECHIAE | | | |

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

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

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

| | | | |
|---|---------------|----------------|-----------------|
| CYTOMEGALOVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION BACTERIAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CANDIDA INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Metabolism and nutrition disorders | | | |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GOUT | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 1 | 2 |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPONATRAEMIA | | | |

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

| Non-serious adverse events | Expansion Phase: 1.4mg Pola + 20mg L + 1000mg G in FL | Expansion Phase: 1.8mg Pola + 20mg L + 375mg R in DLBCL | Dose-escalation Phase: 1.8mg Pola + 10mg L + 1000mg G in FL |
|--|---|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 40 / 40 (100.00%) | 37 / 39 (94.87%) | 4 / 4 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| TUMOUR FLARE | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 1 / 39 (2.56%) | 1 / 4 (25.00%) |
| occurrences (all) | 2 | 1 | 1 |
| SQUAMOUS CELL CARCINOMA | | | |

| | | | |
|---|---------------------|---------------------|--------------------|
| subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Vascular disorders | | | |
| FLUSHING | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| ORTHOSTATIC HYPOTENSION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTENSION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| CHILLS | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 5 | 2 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 13 / 40 (32.50%) | 5 / 39 (12.82%) | 0 / 4 (0.00%) |
| occurrences (all) | 17 | 5 | 0 |
| PAIN | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| FATIGUE | | | |
| subjects affected / exposed | 11 / 40 (27.50%) | 6 / 39 (15.38%) | 0 / 4 (0.00%) |
| occurrences (all) | 11 | 6 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| ASTHENIA | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | 6 / 39 (15.38%) | 2 / 4 (50.00%) |
| occurrences (all) | 12 | 6 | 2 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GAIT DISTURBANCE | | | |

| | | | |
|---|----------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| OEDEMA PERIPHERAL subjects affected / exposed occurrences (all) | 4 / 40 (10.00%) 4 | 2 / 39 (5.13%) 2 | 0 / 4 (0.00%) 0 |
| PERIPHERAL SWELLING subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 3 / 39 (7.69%) 4 | 0 / 4 (0.00%) 0 |
| Immune system disorders HYPOGAMMAGLOBULINAEMIA subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| CYTOKINE RELEASE SYNDROME subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 2 / 39 (5.13%) 2 | 0 / 4 (0.00%) 0 |
| Reproductive system and breast disorders VULVOVAGINAL DRYNESS subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders PRODUCTIVE COUGH subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 2 / 39 (5.13%) 2 | 0 / 4 (0.00%) 0 |
| RHINORRHOEA subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| PLEURAL EFFUSION subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| DYSPNOEA subjects affected / exposed occurrences (all) | 5 / 40 (12.50%) 5 | 1 / 39 (2.56%) 1 | 1 / 4 (25.00%) 1 |
| EPISTAXIS subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 12 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| OROPHARYNGEAL PAIN | | | |

| | | | |
|---------------------------------------|------------------|-----------------|----------------|
| subjects affected / exposed | 4 / 40 (10.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| RHINITIS ALLERGIC | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| UPPER-AIRWAY COUGH SYNDROME | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COUGH | | | |
| subjects affected / exposed | 10 / 40 (25.00%) | 5 / 39 (12.82%) | 0 / 4 (0.00%) |
| occurrences (all) | 11 | 5 | 0 |
| Psychiatric disorders | | | |
| DEPRESSION | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Investigations | | | |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 5 | 2 | 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 3 / 39 (7.69%) | 2 / 4 (50.00%) |
| occurrences (all) | 10 | 4 | 2 |
| BLOOD LACTATE DEHYDROGENASE DECREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CREATININE RENAL CLEARANCE DECREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 4 / 39 (10.26%) | 0 / 4 (0.00%) |
| occurrences (all) | 7 | 8 | 0 |

| | | | |
|--------------------------------------|-----------------|-----------------|----------------|
| CREATININE RENAL CLEARANCE INCREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD GLUCOSE INCREASED | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 12 | 5 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 8 / 40 (20.00%) | 5 / 39 (12.82%) | 1 / 4 (25.00%) |
| occurrences (all) | 11 | 8 | 1 |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 3 / 39 (7.69%) | 0 / 4 (0.00%) |
| occurrences (all) | 10 | 4 | 0 |
| CARDIAC STRESS TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| BLOOD ALKALINE PHOSPHATASE INCREASED | | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| LIPASE INCREASED | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 1 | 1 |
| IMMUNOGLOBULINS DECREASED | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| C-REACTIVE PROTEIN INCREASED | | | |

| | | | |
|--|------------------|----------------|----------------|
| subjects affected / exposed | 2 / 40 (5.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| AMYLASE INCREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Injury, poisoning and procedural complications | | | |
| MUSCLE STRAIN | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 17 / 40 (42.50%) | 2 / 39 (5.13%) | 1 / 4 (25.00%) |
| occurrences (all) | 19 | 2 | 1 |
| FALL | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONTUSION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LEFT VENTRICULAR DYSFUNCTION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| NEURALGIA | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| PERIPHERAL SENSORY NEUROPATHY | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| BURNING SENSATION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| RESTING TREMOR | | | |

| | | | |
|--------------------------------------|------------------|------------------|----------------|
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| PARAESTHESIA | | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 1 / 39 (2.56%) | 1 / 4 (25.00%) |
| occurrences (all) | 4 | 1 | 1 |
| PERIPHERAL MOTOR NEUROPATHY | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DIZZINESS | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 3 / 39 (7.69%) | 0 / 4 (0.00%) |
| occurrences (all) | 7 | 4 | 0 |
| HEAD TITUBATION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUROPATHY PERIPHERAL | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 3 / 39 (7.69%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Blood and lymphatic system disorders | | | |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| NEUTROPHILIA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 26 / 40 (65.00%) | 25 / 39 (64.10%) | 2 / 4 (50.00%) |
| occurrences (all) | 117 | 62 | 9 |

| | | | |
|----------------------------------|------------------|------------------|----------------|
| ANAEMIA | | | |
| subjects affected / exposed | 18 / 40 (45.00%) | 14 / 39 (35.90%) | 0 / 4 (0.00%) |
| occurrences (all) | 29 | 22 | 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 22 / 40 (55.00%) | 10 / 39 (25.64%) | 2 / 4 (50.00%) |
| occurrences (all) | 50 | 18 | 2 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| TYMPANIC MEMBRANE PERFORATION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| OCULAR HYPERAEMIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| VISION BLURRED | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| DRY EYE | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PERIORBITAL OEDEMA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastrointestinal disorders | | | |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

| | | | |
|-----------------------------|-----------------|-----------------|----------------|
| MELAENA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| CONSTIPATION | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | 8 / 39 (20.51%) | 1 / 4 (25.00%) |
| occurrences (all) | 10 | 8 | 1 |
| VOMITING | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 4 / 39 (10.26%) | 0 / 4 (0.00%) |
| occurrences (all) | 5 | 4 | 0 |
| FLATULENCE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ASCITES | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTRITIS | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DRY MOUTH | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UMBILICAL HERNIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 3 / 39 (7.69%) | 0 / 4 (0.00%) |
| occurrences (all) | 5 | 3 | 0 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HAEMORRHOIDAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|------------------|------------------|----------------|
| DIARRHOEA | | | |
| subjects affected / exposed | 17 / 40 (42.50%) | 13 / 39 (33.33%) | 2 / 4 (50.00%) |
| occurrences (all) | 24 | 23 | 2 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 0 | 1 |
| NAUSEA | | | |
| subjects affected / exposed | 8 / 40 (20.00%) | 5 / 39 (12.82%) | 1 / 4 (25.00%) |
| occurrences (all) | 10 | 5 | 2 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 6 / 40 (15.00%) | 3 / 39 (7.69%) | 0 / 4 (0.00%) |
| occurrences (all) | 6 | 3 | 0 |
| ODYNOPHAGIA | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hepatobiliary disorders | | | |
| OCULAR ICTERUS | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| DYSHIDROTIC ECZEMA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 3 / 39 (7.69%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| RASH | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 7 / 39 (17.95%) | 1 / 4 (25.00%) |
| occurrences (all) | 5 | 10 | 1 |
| SKIN ULCER | | | |

| | | | |
|--|----------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 39 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| RASH ERYTHEMATOUS subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 2 / 39 (5.13%) 2 | 0 / 4 (0.00%) 0 |
| PRURITUS subjects affected / exposed occurrences (all) | 4 / 40 (10.00%) 4 | 2 / 39 (5.13%) 3 | 1 / 4 (25.00%) 1 |
| RASH MACULO-PAPULAR subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 3 / 39 (7.69%) 4 | 0 / 4 (0.00%) 0 |
| SKIN EXFOLIATION subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| DRY SKIN subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 2 / 39 (5.13%) 2 | 0 / 4 (0.00%) 0 |
| NIGHT SWEATS subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 4 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| PETECHIAE subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| URTICARIA subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Renal and urinary disorders ACUTE KIDNEY INJURY subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| HAEMATURIA subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| DYSURIA subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 4 | 2 / 39 (5.13%) 2 | 0 / 4 (0.00%) 0 |

| | | | |
|--|----------------------|----------------------|--------------------|
| RENAL FAILURE subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| Endocrine disorders DIABETES INSIPIDUS subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| HYPOTHYROIDISM subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders MUSCLE SPASMS subjects affected / exposed occurrences (all) | 5 / 40 (12.50%) 7 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| TENDONITIS subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| NECK PAIN subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| BACK PAIN subjects affected / exposed occurrences (all) | 5 / 40 (12.50%) 5 | 6 / 39 (15.38%) 7 | 0 / 4 (0.00%) 0 |
| DIASTASIS RECTI ABDOMINIS subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| MUSCULOSKELETAL CHEST PAIN subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 2 / 39 (5.13%) 3 | 0 / 4 (0.00%) 0 |
| ARTHRITIS subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 3 | 1 / 39 (2.56%) 1 | 0 / 4 (0.00%) 0 |
| SACRAL PAIN subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| ARTHRALGIA | | | |

| | | | |
|-----------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 7 / 40 (17.50%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 9 | 2 | 0 |
| MYALGIA | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Infections and infestations | | | |
| SINUSITIS | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| LOWER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| HERPES ZOSTER | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| TONSILLITIS | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 8 / 40 (20.00%) | 2 / 39 (5.13%) | 1 / 4 (25.00%) |
| occurrences (all) | 11 | 2 | 1 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |

| | | | |
|---|-----------------|-----------------|----------------|
| subjects affected / exposed | 6 / 40 (15.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 9 | 2 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 4 / 40 (10.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 1 / 39 (2.56%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 3 / 40 (7.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | 3 / 39 (7.69%) | 1 / 4 (25.00%) |
| occurrences (all) | 13 | 3 | 1 |
| CYTOMEGALOVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION BACTERIAL | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CANDIDA INFECTION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 4 / 39 (10.26%) | 0 / 4 (0.00%) |
| occurrences (all) | 5 | 4 | 0 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|-----------------|-----------------|----------------|
| Metabolism and nutrition disorders | | | |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 4 / 39 (10.26%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |
| GOUT | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 4 / 39 (10.26%) | 1 / 4 (25.00%) |
| occurrences (all) | 6 | 5 | 2 |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 8 / 40 (20.00%) | 6 / 39 (15.38%) | 1 / 4 (25.00%) |
| occurrences (all) | 8 | 6 | 1 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 4 / 39 (10.26%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 7 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| HYPERPHOSPHATAEMIA | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| VITAMIN D DEFICIENCY | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 5 / 39 (12.82%) | 0 / 4 (0.00%) |
| occurrences (all) | 13 | 9 | 0 |
| HYPOPROTEINAEMIA | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 2 / 40 (5.00%) | 2 / 39 (5.13%) | 1 / 4 (25.00%) |
| occurrences (all) | 2 | 2 | 1 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 39 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DYSLIPIDAEMIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 39 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 39 (5.13%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

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