

**Clinical trial results:****A Randomized, Open-Label, Multicenter, Phase II Trial Evaluating the Safety and Activity of Pinatuzumab Vedotin (DCDT2980S) in Combination with Rituximab or Polatuzumab Vedotin (DCDS4501A) in Combination with Rituximab and a Non-Randomized Phase IB/II Evaluation of Polatuzumab Vedotin in Combination with Obinutuzumab in Patients with Relapsed or Refractory B-Cell NonHodgkin's Lymphoma Summary**

| | |
|--------------------------|------------------|
| EudraCT number | 2011-004377-84 |
| Trial protocol | DE IT NL FR |
| Global end of trial date | 07 February 2019 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v3 (current) |
| This version publication date | 02 September 2020 |
| First version publication date | 21 March 2018 |
| Version creation reason | |

Trial information**Trial identification**

| | |
|-----------------------|---------|
| Sponsor protocol code | GO27834 |
|-----------------------|---------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01691898 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | F. Hoffmann-La Roche AG |
| Sponsor organisation address | Grenzacherstrasse 124, Basel, Switzerland, CH-4070 |
| Public contact | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.com |
| Scientific contact | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 07 February 2019 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 February 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Safety, tolerability and anti-tumor activity of pinatuzumab vedotin combined with rituximab and polatuzumab vedotin combined with rituximab or obinutuzumab

Protection of trial subjects:

The study was conducted in accordance with the principles of the "Declaration of Helsinki" and Good Clinical Practice (GCP) according to the regulations and procedures described in different sections of the protocol. Sponsor and the investigators strictly adhered to the stated provisions in these guidelines. This was documented by the investigator's signature on the protocol agreeing to carry out all of its terms in accordance with the applicable regulations and law and to follow International Council for Harmonisation (ICH) GCP guidelines for good clinical practice.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 27 September 2012 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy, Safety |
| Long term follow-up duration | 2 Years |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | France: 23 |
| Country: Number of subjects enrolled | Italy: 16 |
| Country: Number of subjects enrolled | United States: 170 |
| Country: Number of subjects enrolled | Canada: 16 |
| Country: Number of subjects enrolled | Germany: 3 |
| Country: Number of subjects enrolled | Netherlands: 3 |
| Worldwide total number of subjects | 231 |
| EEA total number of subjects | 45 |

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) | 103 |
| From 65 to 84 years | 124 |
| 85 years and over | 4 |

Subject disposition

Recruitment

Recruitment details:

For 4 participants the country was missing and these participants are currently reported under "United States".

Pre-assignment

Screening details:

A total of 289 participants were screened, out of which, 231 participants were enrolled into the study.

Period 1

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

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | Arm A (FL+DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab |

Arm description:

Participants with relapsed or refractory (r/r) follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) received rituximab (RTX) at a dose of 375 milligrams per square meter (mg/m²) administered via intravenous (IV) infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 milligrams per kilogram (mg/kg) administered via IV infusion on Day 2 for the first 2 cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed disease progression (PD) were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Rituximab |
| Investigational medicinal product code | |
| Other name | MabThera/Rituxan |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

RTX 375 mg/m² administered by IV infusion on Day 1 of every 21-day cycle.

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

Dosage and administration details:

Polatuzumab vedotin 2.4 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

| | |
|--|---------------------|
| Investigational medicinal product name | Pinatuzumab Vedotin |
| Investigational medicinal product code | |
| Other name | DCDT2980S |
| Pharmaceutical forms | Powder for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Pinatuzumab vedotin 2.4 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

| | |
|------------------|--|
| Arm title | Arm B (FL+DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
|------------------|--|

Arm description:

Participants with r/r FL and DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Rituximab |
| Investigational medicinal product code | |
| Other name | MabThera/Rituxan |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

RTX 375 mg/m² administered by IV infusion on Day 1 of every 21-day cycle.

| | |
|--|---------------------|
| Investigational medicinal product name | Pinatuzumab Vedotin |
| Investigational medicinal product code | |
| Other name | DCDT2980S |
| Pharmaceutical forms | Powder for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Pinatuzumab vedotin 2.4 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

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

Dosage and administration details:

Polatuzumab vedotin 2.4 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

| | |
|------------------|----------------------------------|
| Arm title | Cohort C (FL): RTX + Polatuzumab |
|------------------|----------------------------------|

Arm description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. In the absence of any infusion-related adverse events, RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle for up to a maximum of 1 year (17 cycles on an every-21-day schedule) or significant toxicity, disease progression, or withdrawal from study.

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

Dosage and administration details:

Polatuzumab vedotin 1.8 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Rituximab |
| Investigational medicinal product code | |
| Other name | MabThera/Rituxan |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

RTX 375 mg/m² administered by IV infusion on Day 1 of every 21-day cycle.

| | |
|------------------|---|
| Arm title | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab |
|------------------|---|

Arm description:

Participants with r/r FL and DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

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

Dosage and administration details:

Polatuzumab vedotin 1.8 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Obinutuzumab |
| Investigational medicinal product code | |
| Other name | GA101, Gazyva, Gazyvaro |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Obinutuzumab 1000 mg administered by IV infusion on Days 1, 8, and 15 of first 21-Day cycle and on Day 1 of subsequent 21-day cycles for up to 8 cycles.

| | |
|------------------|--|
| Arm title | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab |
|------------------|--|

Arm description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Obinutuzumab |
| Investigational medicinal product code | |
| Other name | GA101, Gazyva, Gazyvaro |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Obinutuzumab 1000 mg administered by IV infusion on Days 1, 8, and 15 of first 21-Day cycle and on Day 1 of subsequent 21-day cycles for up to 8 cycles.

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

Dosage and administration details:

Polatuzumab vedotin 1.8 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

| | |
|------------------|---|
| Arm title | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|------------------|---|

Arm description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Obinutuzumab |
| Investigational medicinal product code | |
| Other name | GA101, Gazyva, Gazyvaro |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Obinutuzumab 1000 mg administered by IV infusion on Days 1, 8, and 15 of first 21-Day cycle and on Day 1 of subsequent 21-day cycles for up to 8 cycles.

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

Dosage and administration details:

Polatuzumab vedotin 1.8 mg/kg administered by IV infusion on Day 1 or 2 of every 21-day cycle.

| Number of subjects in period 1 | Arm A (FL+DLBCL): RTX+Pinatuzumab, then RTX+Polatuzumab | Arm B (FL+DLBCL): RTX+Polatuzumab, then RTX+Pinatuzumab | Cohort C (FL): RTX + Polatuzumab |
|---------------------------------------|---|---|-------------------------------------|
| Started | 63 | 59 | 20 |
| Completed | 16 | 15 | 11 |
| Not completed | 47 | 44 | 9 |
| Consent withdrawn by subject | 9 | 8 | 2 |
| Progression of Disease | 1 | 2 | 1 |
| Adverse Event | - | 1 | - |
| Death | 34 | 32 | 6 |
| Non-compliance | - | - | - |
| Lost to follow-up | 3 | 1 | - |

| Number of subjects in period 1 | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|---------------------------------------|--|---|--|
| Started | 9 | 40 | 40 |
| Completed | 4 | 26 | 5 |
| Not completed | 5 | 14 | 35 |
| Consent withdrawn by subject | 1 | 3 | 3 |
| Progression of Disease | - | - | 1 |
| Adverse Event | 1 | 1 | - |
| Death | 3 | 8 | 31 |
| Non-compliance | - | 1 | - |
| Lost to follow-up | - | 1 | - |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Arm A (FL+DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab |
|-----------------------|--|

Reporting group description:

Participants with relapsed or refractory (r/r) follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) received rituximab (RTX) at a dose of 375 milligrams per square meter (mg/m²) administered via intravenous (IV) infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 milligrams per kilogram (mg/kg) administered via IV infusion on Day 2 for the first 2 cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed disease progression (PD) were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|-----------------------|--|
| Reporting group title | Arm B (FL+DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
|-----------------------|--|

Reporting group description:

Participants with r/r FL and DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|-----------------------|----------------------------------|
| Reporting group title | Cohort C (FL): RTX + Polatuzumab |
|-----------------------|----------------------------------|

Reporting group description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. In the absence of any infusion-related adverse events, RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle for up to a maximum of 1 year (17 cycles on an every-21-day schedule) or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|---|
| Reporting group title | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab |
|-----------------------|---|

Reporting group description:

Participants with r/r FL and DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|--|
| Reporting group title | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab |
|-----------------------|--|

Reporting group description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|---|
| Reporting group title | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|-----------------------|---|

Reporting group description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| Reporting group values | Arm A (FL+DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab | Arm B (FL+DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab | Cohort C (FL): RTX + Polatuzumab |
|------------------------------------|--|--|-------------------------------------|
| Number of subjects | 63 | 59 | 20 |
| Age Categorical Units: Subjects | | | |

| | | | |
|---|----------------|----------------|---------------|
| Age Continuous Units: years arithmetic mean standard deviation | 65.1 ± 11.1 | 65.5 ± 13.6 | 61.0 ± 9.9 |
| Gender Categorical Units: Subjects | | | |
| Female | 27 | 24 | 8 |
| Male | 36 | 35 | 12 |

| Reporting group values | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|------------------------------------|--|---|--|
| Number of subjects | 9 | 40 | 40 |
| Age Categorical Units: Subjects | | | |

| | | | |
|---|---------------|----------------|----------------|
| Age Continuous Units: years arithmetic mean standard deviation | 67.7 ± 9.7 | 63.0 ± 12.6 | 65.2 ± 15.3 |
| Gender Categorical Units: Subjects | | | |
| Female | 2 | 16 | 18 |
| Male | 7 | 24 | 22 |

| Reporting group values | Total | | |
|------------------------------------|-------|--|--|
| Number of subjects | 231 | | |
| Age Categorical Units: Subjects | | | |

| | | | |
|---|-----|--|--|
| Age Continuous Units: years arithmetic mean standard deviation | - | | |
| Gender Categorical Units: Subjects | | | |
| Female | 95 | | |
| Male | 136 | | |

Subject analysis sets

| | |
|----------------------------|---|
| Subject analysis set title | Arm A (DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|--|
| Subject analysis set title | Arm A (FL): RTX+Pinatuzumab,Then RTX+Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|---|
| Subject analysis set title | Arm B (DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|--|
| Subject analysis set title | Arm B (FL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|--|
| Subject analysis set title | Cohort E (DLBCL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------------------------|---|
| Subject analysis set title | Cohort E (FL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------------------------|--|
| Subject analysis set title | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15

and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------------------------|---|
| Subject analysis set title | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| Reporting group values | Arm A (DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab | Arm A (FL): RTX+Pinatuzumab,Then RTX+Polatuzumab | Arm B (DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
|------------------------------------|---|--|---|
| Number of subjects | 42 | 21 | 39 |
| Age Categorical Units: Subjects | | | |

| | | | |
|---|----------------|----------------|----------------|
| Age Continuous Units: years arithmetic mean standard deviation | 67.0 ± 11.1 | 61.1 ± 10.3 | 64.8 ± 14.7 |
| Gender Categorical Units: Subjects | | | |
| Female | 16 | 11 | 14 |
| Male | 26 | 10 | 25 |

| Reporting group values | Arm B (FL): RTX+Polatuzumab,Then RTX+Pinatuzumab | Cohort E (DLBCL): Obinutuzumab + Polatuzumab | Cohort E (FL): Obinutuzumab + Polatuzumab |
|------------------------------------|--|--|---|
| Number of subjects | 20 | 5 | 4 |
| Age Categorical Units: Subjects | | | |

| | | | |
|---|----------------|----------------|---------------|
| Age Continuous Units: years arithmetic mean standard deviation | 66.8 ± 11.6 | 69.0 ± 11.6 | 66.0 ± 8.1 |
| Gender Categorical Units: Subjects | | | |
| Female | 10 | 2 | 0 |
| Male | 10 | 3 | 4 |

| Reporting group values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | |
|------------------------------------|--|--|--|
| Number of subjects | 44 | 45 | |
| Age Categorical Units: Subjects | | | |

| | | | |
|--------------------|--------|--------|--|
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 63.3 | 65.6 | |
| standard deviation | ± 12.2 | ± 14.9 | |
| Gender Categorical | | | |
| Units: Subjects | | | |
| Female | 16 | 20 | |
| Male | 28 | 25 | |

End points

End points reporting groups

| | |
|-----------------------|--|
| Reporting group title | Arm A (FL+DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab |
|-----------------------|--|

Reporting group description:

Participants with relapsed or refractory (r/r) follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) received rituximab (RTX) at a dose of 375 milligrams per square meter (mg/m²) administered via intravenous (IV) infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 milligrams per kilogram (mg/kg) administered via IV infusion on Day 2 for the first 2 cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed disease progression (PD) were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|-----------------------|--|
| Reporting group title | Arm B (FL+DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
|-----------------------|--|

Reporting group description:

Participants with r/r FL and DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|-----------------------|----------------------------------|
| Reporting group title | Cohort C (FL): RTX + Polatuzumab |
|-----------------------|----------------------------------|

Reporting group description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. In the absence of any infusion-related adverse events, RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle for up to a maximum of 1 year (17 cycles on an every-21-day schedule) or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|---|
| Reporting group title | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab |
|-----------------------|---|

Reporting group description:

Participants with r/r FL and DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|--|
| Reporting group title | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab |
|-----------------------|--|

Reporting group description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|---|
| Reporting group title | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|-----------------------|---|

Reporting group description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------------------------|---|
| Subject analysis set title | Arm A (DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab |
|----------------------------|---|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

Subject analysis set description:

Participants with r/r DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2

cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|--|
| Subject analysis set title | Arm A (FL): RTX+Pinatuzumab,Then RTX+Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|---|
| Subject analysis set title | Arm B (DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|--|
| Subject analysis set title | Arm B (FL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|----------------------------|--|
| Subject analysis set title | Cohort E (DLBCL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------------------------|---|
| Subject analysis set title | Cohort E (FL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------------------------|--|
| Subject analysis set title | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|----------------------------|---|
| Subject analysis set title | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

Primary: Percentage of Participants with a Best Overall Response (OR) of Complete Response (CR) or Partial Response (PR) as Determined by Modified Response and Progression Criteria for NHL: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|---|
| End point title | Percentage of Participants with a Best Overall Response (OR) of Complete Response (CR) or Partial Response (PR) as Determined by Modified Response and Progression Criteria for NHL: Rituximab Containing Regimens (Arms A and B, Cohort C) ^{[1][2]} |
|-----------------|---|

End point description:

Tumor response was evaluated according to modified response and progression criteria for NHL published by Cheson et al (2007 and 2014) and confirmed by repeat assessments greater than or equal to (\geq) 4 weeks after initial documentation. CR was defined as disappearance of all clinical/radiographic evidence of disease, regression of lymph nodes to normal size, absence of splenomegaly, and absence of bone marrow involvement. PR was defined as ≥ 50 percent (%) decrease in sum of the products of greatest diameters (SPD) of up to six of the largest dominant lymph nodes, no increase in size of other nodes, liver, or spleen volume, a $\geq 50\%$ decrease in SPD of hepatic and splenic nodules, absence of other organ involvement, and no new sites of disease. Analysis was performed on efficacy-evaluable population, which included all participants with baseline measurable disease and at least one post-baseline tumor assessment.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Baseline up to 12 months after the last dose of study treatment (up to approximately 3.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

[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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|-----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 20 | 42 | 21 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 75.0 (54.44 to 89.59) | 59.5 (45.67 to 72.32) | 61.9 (41.72 to 79.43) | 53.8 (39.58 to 67.65) |

| | | | | |
|------------------|--|--|--|--|
| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
|------------------|--|--|--|--|

| | | | | |
|-----------------------------------|-----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 20 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 70.0 (49.22 to 86.04) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Duration of Objective Response (DOR) as Determined by Modified Response and Progression Criteria for NHL: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|--|
| End point title | Duration of Objective Response (DOR) as Determined by Modified Response and Progression Criteria for NHL: Rituximab Containing Regimens (Arms A and B, Cohort C) ^{[3][4]} |
|-----------------|--|

End point description:

Tumor response was evaluated according to modified response and progression criteria for NHL published by Cheson et al (2007 and 2014). DOR was defined as the time from the initial documentation of a CR or PR to the time of PD or death. CR was defined as disappearance of all clinical/radiographic evidence of disease, regression of lymph nodes to normal size, absence of splenomegaly, and absence of bone marrow involvement. PR was defined as $\geq 50\%$ decrease in SPD of up to six of the largest dominant lymph nodes, no increase in size of other nodes, liver, or spleen volume, a $\geq 50\%$ decrease in SPD of hepatic and splenic nodules, absence of other organ involvement, and no new sites of disease. PD was defined as appearance of any new lesion more than 1.5 centimeters (cm) in any axis, at least a 50% increase from nadir in the SPD or longest diameter of any previous lesion or node. Analysis was performed on efficacy-evaluable population participants who achieved objective response.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

First occurrence of objective response up to PD/relapse or death due to any cause, whichever occurred first (up to approximately 3.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|-------------------------------|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 15 | 25 | 13 | 21 |
| Units: months | | | | |
| median (full range (min-max)) | 12.85 (0.03 to 22.11) | 6.24 (0.89 to 22.57) | 6.47 (0.03 to 23.52) | 13.37 (0.03 to 35.68) |

| | | | | |
|------------------|---|--|--|--|
| End point values | Arm B (FL): RTX+Polatuzu mab,Then | | | |
|------------------|---|--|--|--|

| | | | | |
|-------------------------------|-------------------------|--|--|--|
| | RTX+Pinatuzu mab | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 14 | | | |
| Units: months | | | | |
| median (full range (min-max)) | 9.36 (0.03 to 19.35) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with CR at End of Treatment (EOT) Based on Positron Emission Tomographic/Computed Tomography (PET/CT) Assessment Determined by Independent Review Committee (IRC) per Lugano 2014 Response Criteria: Cohorts E, G, and H

| | |
|-----------------|---|
| End point title | Percentage of Participants with CR at End of Treatment (EOT) Based on Positron Emission Tomographic/Computed Tomography (PET/CT) Assessment Determined by Independent Review Committee (IRC) per Lugano 2014 Response Criteria: Cohorts E, G, and H ^{[5][6]} |
|-----------------|---|

End point description:

Tumor response assessment was performed by an IRC according to modified Lugano classification using PET/CT scan. CR was defined as a score of 1 (no uptake above background), 2 (uptake less than or equal to [\leq] mediastinum), or 3 (uptake less than [$<$] mediastinum but \leq liver) with or without a residual mass on PET 5-point scale (5-PS), for lymph nodes and extralymphatic sites; no new lesions; no evidence of fluorodeoxyglucose (FDG)-avid disease in bone marrow; and normal/immunohistochemistry (IHC)-negative bone marrow morphology. 90% confidence interval (CI) for percentage of responders was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Reported analysis was planned to be carried out in the indicated arms only.

[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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab | Cohort E (DLBCL): Obinutuzumab + Polatuzumab | Cohort E (FL): Obinutuzumab + Polatuzumab |
|-----------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 34 | 27 | 4 | 2 |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 35.3 (21.79 to 50.82) | 0 (0.0 to 10.50) | 0 (0.0 to 52.71) | 50.0 (2.53 to 97.47) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-Drug Antibodies (ADA) to Pinatuzumab Vedotin

| | |
|-----------------|--|
| End point title | Number of Participants with Anti-Drug Antibodies (ADA) to Pinatuzumab Vedotin ^[7] |
|-----------------|--|

End point description:

The number of participants with positive results for ADA against pinatuzumab vedotin at Baseline and at any of the post-baseline assessment time-points (overall 1.5 years) was reported. Participants positive at any post-baseline time points: post-baseline evaluable participants determined to have "Treatment-induced ADAs" or "Treatment-enhanced ADA". Treatment-induced ADA: participant with negative or missing Baseline ADA result(s) and at least 1 positive post-Baseline ADA result. Treatment-enhanced ADA: participant with positive ADA result at Baseline who has ≥ 1 post Baseline titer results that are at least 0.60 titer unit greater than the Baseline result. Analysis was performed on safety-evaluable population, which included all participants who received at least 1 dose of study treatment (pinatuzumab vedotin). Here, 'Number of Subjects Analysed'=participants evaluable for this outcome measure; 'n'=participants evaluable at specified time points for each group, respectively.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, post-baseline (up to approximately 5.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Arm A (FL+DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (FL+DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | |
|-----------------------------|---|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 60 | 1 | | |
| Units: participants | | | | |
| Baseline (n=60, 0) | 2 | 0 | | |
| Post-baseline (n=56, 1) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with ADA to Polatuzumab Vedotin

| | |
|-----------------|--|
| End point title | Number of Participants with ADA to Polatuzumab Vedotin |
|-----------------|--|

End point description:

The number of participants with positive results for ADA against polatuzumab vedotin at Baseline and at any of the post-baseline assessment time-points (overall 1.5 years) was reported. Participants positive at any post-baseline time points were post-baseline evaluable participants determined to have "Treatment-induced ADAs" or "Treatment-enhanced ADA" during the study. Treatment-induced ADA: participant with negative or missing Baseline ADA result(s) and at least 1 positive post-Baseline ADA result. Treatment-enhanced ADA: participant with positive ADA result at Baseline who has ≥ 1 post Baseline titer results that are at least 0.60 titer unit greater than the Baseline result. Analysis was performed on safety-evaluable population (only participants who received polatuzumab vedotin). Here, 'Number of Subjects Analysed'=participants evaluable for this outcome measure and 'n'=participants evaluable at specified time points for each group, respectively.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, post-baseline (up to approximately 5.5 years) | |

| End point values | Arm A (FL+DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (FL+DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | Cohort C (FL): RTX + Polatuzumab | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab |
|-----------------------------------|---|---|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 59 | 20 | 8 |
| Units: participants | | | | |
| Baseline (n=0,59,20,8,37,36) | 0 | 1 | 0 | 0 |
| Post-baseline (n=2,53,20,6,36,36) | 0 | 0 | 0 | 0 |

| End point values | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------------|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 37 | 36 | | |
| Units: participants | | | | |
| Baseline (n=0,59,20,8,37,36) | 0 | 0 | | |
| Post-baseline (n=2,53,20,6,36,36) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with ADA to Obinutuzumab

| | |
|-----------------|--|
| End point title | Number of Participants with ADA to Obinutuzumab ^[8] |
|-----------------|--|

End point description:

The number of participants with positive results for ADA against obinutuzumab at Baseline and at any of the post-baseline assessment time-points (overall 1.5 years) was reported. Participants positive at any post-baseline time points were post-baseline evaluable participants determined to have "Treatment-induced ADAs" or "Treatment-enhanced ADA" during the study. Treatment-induced ADA: participant with negative or missing Baseline ADA result(s) and at least 1 positive post-Baseline ADA result. Treatment-enhanced ADA: participant with positive ADA result at Baseline who has ≥ 1 post Baseline titer results that are at least 0.60 titer unit greater than the Baseline result. Analysis was performed on safety-evaluable population (only participants who received obinutuzumab). Here, 'Number of Subjects Analysed'=participants evaluable for this outcome measure and 'n'=participants evaluable at specified time points for each group, respectively.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, post-baseline (up to approximately 5.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab | |
|-----------------------------|--|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 37 | 39 | |
| Units: participants | | | | |
| Baseline (n=9,37,39) | 1 | 2 | 0 | |
| Post-baseline (n=6,36,37) | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with PD as Determined by Modified Response and Progression Criteria for NHL or Death due to any Cause: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|---|
| End point title | Percentage of Participants with PD as Determined by Modified Response and Progression Criteria for NHL or Death due to any Cause: Rituximab Containing Regimens (Arms A and B, Cohort C) ^[9] |
|-----------------|---|

End point description:

Tumor response was evaluated according to modified response and progression criteria for NHL published by Cheson et al (2007 and 2014) and confirmed by repeat assessments ≥ 4 weeks after initial documentation. PD was defined as appearance of any new lesion more than 1.5 cm in any axis, at least a 50% increase from nadir in the SPD or longest diameter of any previous lesion or node. Analysis was performed on efficacy-evaluable population.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 5.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|-----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 20 | 42 | 21 | 39 |
| Units: percentage of participants | | | | |
| number (not applicable) | 60.0 | 85.7 | 52.4 | 76.9 |

| | | | | |
|-----------------------------------|--|--|--|--|
| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 20 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 55.0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) as Determined by Modified Response and Progression Criteria for NHL: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|---|
| End point title | Progression-free Survival (PFS) as Determined by Modified Response and Progression Criteria for NHL: Rituximab Containing Regimens (Arms A and B, Cohort C) ^[10] |
|-----------------|---|

End point description:

Tumor response was evaluated according to modified response and progression criteria for NHL published by Cheson et al (2007 and 2014) and confirmed by repeat assessments ≥ 4 weeks after initial documentation. PD was defined as appearance of any new lesion more than 1.5 cm in any axis, at least a 50% increase from nadir in the SPD or longest diameter of any previous lesion or node. PFS was defined as the time from the date of randomization to the date of PD or death from any cause, whichever occurred first. In absence of PD or death, PFS was censored at the date of the last tumor assessment. Participants with no post-baseline tumor assessment were censored on the date of randomization or date of enrollment. The median PFS was estimated using Kaplan-Meier estimates and the 95% CI for median was computed using the method of Brookmeyer and Crowley. Analysis was performed on efficacy-evaluable population.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 5.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

| | | | | |
|----------------------------------|--|--|--|--|
| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 20 | 42 | 21 | 39 |
| Units: months | | | | |
| median (confidence interval 95%) | 18.103 (11.598 to 30.259) | 5.388 (3.943 to 10.579) | 12.682 (8.936 to 27.466) | 5.552 (4.304 to 12.780) |

| | | | | |
|----------------------------------|--|--|--|--|
| End point values | Arm B (FL): RTX+Polatuzumab,Then RTX+Pinatuzumab | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 20 | | | |
| Units: months | | | | |
| median (confidence interval 95%) | 15.277 (12.189 to 25.133) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Died due to any Cause: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|--|
| End point title | Percentage of Participants who Died due to any Cause: Rituximab Containing Regimens (Arms A and B, Cohort C) ^[11] |
|-----------------|--|

End point description:

Percentage of participants who died due to any cause was reported. Analysis was performed on efficacy-evaluable population.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to death due to any cause (from baseline up to study completion date, up to approximately 5.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

| | | | | |
|-----------------------------------|--|--|--|--|
| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab | Arm A (FL): RTX+Pinatuzumab,Then RTX+Polatuzumab | Arm B (DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 20 | 42 | 21 | 39 |
| Units: percentage of participants | | | | |
| number (not applicable) | 20.0 | 66.7 | 23.8 | 61.5 |

| | | | | |
|-----------------------------------|--|--|--|--|
| End point values | Arm B (FL): RTX+Polatuzumab,Then RTX+Pinatuzumab | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 20 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 15.0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS): Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|---|
| End point title | Overall Survival (OS): Rituximab Containing Regimens (Arms A and B, Cohort C) ^[12] |
|-----------------|---|

End point description:

OS was defined as the time from the date of randomization or enrollment to the date of death from any cause. The median OS was estimated using Kaplan-Meier estimates and the 95% CI for median was computed using the method of Brookmeyer and Crowley. Analysis was performed on efficacy-evaluable population. The data '99.999 (9.9999 to 999.99)' in the results signifies that median and corresponding CI could not be calculated because very few participants (<50%) had the event of interest.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to death due to any cause (from baseline up to study completion date, up to approximately 5.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 20 | 42 | 21 | 39 |
| Units: months | | | | |
| median (confidence interval 95%) | 99.999 (9.9999 to 999.99) | 16.493 (7.458 to 32.460) | 99.999 (44.025 to 999.99) | 18.760 (10.415 to 38.571) |

| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
|----------------------------------|--|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 20 | | | |
| Units: months | | | | |
| median (confidence interval 95%) | 99.999 (9.9999 to 999.99) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With CR at EOT Based on PET/CT Assessment as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H)

| | |
|-----------------|---|
| End point title | Percentage of Participants With CR at EOT Based on PET/CT Assessment as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H) ^[13] |
|-----------------|---|

End point description:

Tumor response assessment was performed by the investigator according to modified Lugano classification using PET/CT scan. CR was defined as a score of 1 (no uptake above background), 2 (uptake \leq mediastinum), or 3 (uptake $<$ mediastinum but \leq liver) with or without a residual mass on PET 5-PS, for lymph nodes and extralymphatic sites; no new lesions; no evidence of FDG-avid disease in bone marrow; and normal/IHC-negative bone marrow morphology. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab | Cohort E (DLBCL): Obinutuzumab + Polatuzumab | Cohort E (FL): Obinutuzumab + Polatuzumab |
|-----------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 36 | 33 | 4 | 3 |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 33.3 (20.49 to 48.34) | 15.2 (6.17 to 29.25) | 25.0 (1.27 to 75.14) | 66.7 (13.54 to 98.30) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with OR at EOT Based on PET/CT Assessment as Determined by IRC per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H)

| | |
|-----------------|---|
| End point title | Percentage of Participants with OR at EOT Based on PET/CT |
|-----------------|---|

End point description:

Tumor response assessment was performed by an IRC according to modified Lugano classification using PET/CT scan. OR was defined as a response of CR or PR. CR: a score of 1 (no uptake above background), 2 (uptake \leq mediastinum), or 3 (uptake $<$ mediastinum but \leq liver) with or without a residual mass on PET 5-PS, for lymph nodes and extralymphatic sites; no new lesions; no evidence of FDG-avid disease in bone marrow; and normal/IHC-negative bone marrow morphology. PR: a score 4 (uptake moderately greater than $>$ liver) or 5 (uptake markedly $>$ liver and/or new lesions) with reduced uptake compared with baseline and residual mass(es) of any size on PET 5-PS for lymph nodes and extralymphatic sites; no new lesions; and reduced residual uptake in bone marrow compared with baseline. 90% CI was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population; 'Number of Subjects Analysed'=participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab | Cohort E (DLBCL): Obinutuzumab + Polatuzumab | Cohort E (FL): Obinutuzumab + Polatuzumab |
|-----------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 34 | 27 | 4 | 2 |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 64.7 (49.18 to 78.21) | 18.5 (7.59 to 35.06) | 25.0 (1.27 to 75.14) | 100.0 (22.36 to 100.00) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with OR at EOT Based on PET/CT Assessment as Determined by the Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H)

| | |
|-----------------|---|
| End point title | Percentage of Participants with OR at EOT Based on PET/CT Assessment as Determined by the Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H) ^[15] |
|-----------------|---|

End point description:

Tumor response assessment was performed by investigator according to modified Lugano classification using PET/CT scan. OR was defined as a response of CR or PR. CR: a score of 1 (no uptake above background), 2 (uptake \leq mediastinum), or 3 (uptake $<$ mediastinum but \leq liver) with or without a residual mass on PET 5-PS, for lymph nodes and extralymphatic sites; no new lesions; no evidence of FDG-avid disease in bone marrow; and normal/IHC-negative bone marrow morphology. PR: a score 4 (uptake moderately $>$ liver) or 5 (uptake markedly $>$ liver and/or new lesions) with reduced uptake compared with baseline and residual mass(es) of any size on PET 5-PS for lymph nodes and extralymphatic sites; no new lesions; and reduced residual uptake in bone marrow compared with baseline. 90% CI for was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population; 'Number of Subjects Analysed'=participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab | Cohort E (DLBCL): Obinutuzumab + Polatuzumab | Cohort E (FL): Obinutuzumab + Polatuzumab |
|-----------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 36 | 33 | 4 | 3 |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 63.9 (48.83 to 77.15) | 21.2 (10.40 to 36.18) | 25.0 (1.27 to 75.14) | 66.7 (13.54 to 98.30) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR at EOT Based on CT Assessment Alone as Determined by IRC per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G)

| | |
|-----------------|--|
| End point title | Percentage of Participants with CR at EOT Based on CT Assessment Alone as Determined by IRC per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G) |
|-----------------|--|

End point description:

Tumor response assessment was performed by an IRC according to modified Lugano classification using CT scan. CR was defined as reduction of longest transverse diameter (LDi) of target nodes/nodal masses to less than or equal to (\leq) 1.5 cm, no extralymphatic sites of disease, absence of non-measured lesions and new lesions, reduction of enlarged organs to normal, and normal/IHC-negative bone marrow morphology. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------------|---|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 36 | 31 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 13.9 (5.6 to | 6.5 (1.2 to | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR at EOT Based on CT Assessment Alone as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G)

| | |
|-----------------|---|
| End point title | Percentage of Participants with CR at EOT Based on CT Assessment Alone as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G) |
|-----------------|---|

End point description:

Tumor response assessment was performed by investigator according to modified Lugano classification using CT scan. CR was defined as reduction of LD_i of target nodes/nodal masses to ≤ 1.5 cm, no extralymphatic sites of disease, absence of non-measured lesions and new lesions, reduction of enlarged organs to normal, and normal/IHC-negative bone marrow morphology. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 37 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 20.5 (10.6 to 34.0) | 10.8 (3.8 to 23.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with OR at EOT Based on CT Assessment Alone as Determined by IRC per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G)

| | |
|-----------------|--|
| End point title | Percentage of Participants with OR at EOT Based on CT Assessment Alone as Determined by IRC per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G) |
|-----------------|--|

End point description:

Tumor response assessment was performed by an IRC according to modified Lugano classification using CT scan. OR was defined as a response of CR or PR. CR was defined as reduction of LD_i of target nodes/nodal masses to ≤ 1.5 cm, no extralymphatic sites of disease, absence of non-measured lesions and new lesions, reduction of enlarged organs to normal, and normal/IHC-negative bone marrow morphology. PR was defined as $\geq 50\%$ decrease in SPD of up to 6 target measurable nodes and extra-nodal sites; absence/reduction/no increase in size of non-measured lesions; reduction in length of spleen by at least $>50\%$ beyond normal; and no new lesions. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population. Here, 'Number of Subjects Analysed'=participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 36 | 31 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 66.7 (51.7 to 79.5) | 25.8 (13.5 to 41.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with OR at EOT Based on CT Assessment Alone as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G)

| | |
|-----------------|---|
| End point title | Percentage of Participants with OR at EOT Based on CT Assessment Alone as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G) |
|-----------------|---|

End point description:

Tumor response assessment was performed by investigator according to modified Lugano classification using CT scan. OR was defined as a response of CR or PR. CR was defined as reduction of LD_i of target nodes/nodal masses to ≤ 1.5 cm, no extralymphatic sites of disease, absence of non-measured lesions and new lesions, reduction of enlarged organs to normal, and normal/IHC-negative bone marrow morphology. PR was defined as $\geq 50\%$ decrease in SPD of up to 6 target measurable nodes and extra-nodal sites; absence/reduction/no increase in size of non-measured lesions; reduction in length of spleen by at least $>50\%$ beyond normal; and no new lesions. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population. Here, 'Number of Subjects Analysed'=participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6-8 weeks after Cycle 8 Day 1 (cycle length = 21 Days) or last study treatment (maximum up to 27-29 weeks)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 37 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 64.1 (49.7 to 76.8) | 21.6 (11.2 to 35.6) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Best OR Based on PET/CT or CT Assessment as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H)

| | |
|-----------------|---|
| End point title | Percentage of Participants with Best OR Based on PET/CT or CT Assessment as Determined by Investigator per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H) ^[16] |
|-----------------|---|

End point description:

Tumor response assessment was performed by investigator according to modified Lugano classification using PET/CT or CT scan. Best OR was defined as a response of CR or PR. CR: a score of 1 (no uptake above background), 2 (uptake \leq mediastinum), or 3 (uptake $<$ mediastinum but \leq liver) with or without a residual mass on PET 5-PS, for lymph nodes and extralymphatic sites; no new lesions; no evidence of FDG-avid disease in bone marrow; and normal/IHC-negative bone marrow morphology. PR: a score 4 (uptake moderately $>$ liver) or 5 (uptake markedly $>$ liver and/or new lesions) with reduced uptake compared with baseline and residual mass(es) of any size on PET 5-PS for lymph nodes and extralymphatic sites; no new lesions; and reduced residual uptake in bone marrow compared with baseline. 90% CI was calculated using Clopper-Pearson method. Analysis was performed on efficacy-evaluable population; 'Number of Subjects Analysed'=participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to disease progression or death, whichever occurred first (up to approximately 5.5 years)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab | Cohort E (DLBCL): Obinutuzumab + Polatuzumab | Cohort E (FL): Obinutuzumab + Polatuzumab |
|-----------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 39 | 39 | 5 | 4 |
| Units: percentage of participants | | | | |
| number (confidence interval 90%) | 74.4 (60.40 to 85.38) | 43.6 (30.0 to 57.94) | 20.0 (1.02 to 65.74) | 50.0 (9.76 to 90.24) |

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-Time Curve From Time Zero to Infinity (AUCinf) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|--|
| End point title | Area Under the Concentration-Time Curve From Time Zero to Infinity (AUCinf) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C) ^[17] |
|-----------------|--|

End point description:

AUCinf for rituximab was estimated from serum concentration data using non-compartmental analysis. Analysis was performed on all participants with measurable pharmacokinetic (PK) concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes post-infusion (infusion length= 2-6 hours) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 days)

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: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|---|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 15 | 25 | 15 | 26 |
| Units: day*micrograms (mcg)/milliliter (mL) | | | | |
| arithmetic mean (standard deviation) | 2660 (± 879) | 5640 (± 8320) | 3350 (± 1180) | 4200 (± 2620) |

| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
|---|--|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 11 | | | |
| Units: day*micrograms (mcg)/milliliter (mL) | | | | |
| arithmetic mean (standard deviation) | 3910 (± 2480) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Serum Concentration (C_{max}) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|---|
| End point title | Maximum Observed Serum Concentration (C _{max}) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C) ^[18] |
|-----------------|---|

End point description:

C_{max} for rituximab was estimated from serum concentration data using non-compartmental analysis. Analysis was performed on all participants with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes post-infusion (infusion length= 2-6 hours) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 days)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|--------------------------------------|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 18 | 36 | 18 | 35 |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 227 (± 32.4) | 217 (± 61.5) | 225 (± 40.9) | 232 (± 72.7) |

| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
|--------------------------------------|--|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 16 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 228 (± 83.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Systemic Clearance (CL) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|--|
| End point title | Systemic Clearance (CL) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C) ^[19] |
|-----------------|--|

End point description:

CL for rituximab was estimated from serum concentration data using non-compartmental analysis. Analysis was performed on all participants with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes post-infusion (infusion length= 2-6 hours) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 days)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|--|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 15 | 25 | 15 | 26 |
| Units: mL/day/meter-square (m ²) | | | | |
| arithmetic mean (standard deviation) | 158.57 (± 60.47) | 113.97 (± 61.41) | 124.53 (± 41.12) | 116.26 (± 59.99) |

| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
|--|--|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 11 | | | |
| Units: mL/day/meter-square (m ²) | | | | |
| arithmetic mean (standard deviation) | 134.31 (± 97.45) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Half-Life (t_{1/2}) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|---|
| End point title | Half-Life (t _{1/2}) of Rituximab: Rituximab Containing Regimens |
|-----------------|---|

End point description:

t_{1/2} for rituximab was estimated from serum concentration data using non-compartmental analysis. Analysis was performed on all participants with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure. Time Frame: Pre-infusion (Hour 0) & 30 minutes post-infusion (infusion length= 2-6 hours) on Day 1 of Cycle 1-4 and every 4th Cycle thereafter (approximately up to 1.5 years); Day 8, Day 15 of Cycle 1 and 3; 30 Days after last infusion; 2, 4, & 6 months after treatment completion visit (approximately up to 1.5 years, Cycle length= 21 days).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 1 up to 1.5 years (detailed timeframe is provided in the Description)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|--------------------------------------|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 15 | 25 | 15 | 26 |
| Units: days | | | | |
| arithmetic mean (standard deviation) | 14.4 (± 3.62) | 35.3 (± 56.3) | 18.7 (± 6.23) | 25.6 (± 18.0) |

| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
|--------------------------------------|--|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 11 | | | |
| Units: days | | | | |
| arithmetic mean (standard deviation) | 19.8 (± 7.34) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution at Steady State (V_{ss}) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

| | |
|-----------------|--|
| End point title | Volume of Distribution at Steady State (V _{ss}) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C) ^[21] |
|-----------------|--|

End point description:

V_{ss} for rituximab was estimated from serum concentration data using non-compartmental analysis. Analysis was performed on all participants with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure. Time Frame: Pre-infusion (Hour 0) & 30 minutes post-infusion (infusion length= 2-6 hours) on Day 1 of Cycle 1-4 and every 4th Cycle thereafter (approximately up to 1.5 years); Day 8, Day 15 of Cycle 1 and 3; 30

Days after last infusion; 2, 4, & 6 months after treatment completion visit (approximately up to 1.5 years, Cycle length= 21 days)

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 1 up to 1.5 years (detailed timeframe is provided in the end point description)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm B (DLBCL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab |
|--------------------------------------|--|--|--|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 15 | 25 | 15 | 26 |
| Units: mL/m ² | | | | |
| arithmetic mean (standard deviation) | 2654.46 (± 413.19) | 2901.85 (± 1009.31) | 2802.96 (± 678.33) | 2988.90 (± 788.89) |

| End point values | Arm B (FL): RTX+Polatuzu mab,Then RTX+Pinatuzu mab | | | |
|--------------------------------------|--|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 11 | | | |
| Units: mL/m ² | | | | |
| arithmetic mean (standard deviation) | 2839.26 (± 730.10) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of Total Antibody for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUCinf of Total Antibody for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

AUCinf of total antibody for pinatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with Monomethyl Auristatin E (MMAE)-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received pinatuzumab vedotin (Arm A) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 27 | 15 | | |
| Units: day*mcg/mL | | | | |
| arithmetic mean (standard deviation) | 309 (± 67.7) | 315 (± 111) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of Antibody Conjugated Monomethyl Auristatin E (acMMAE) for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUCinf of Antibody Conjugated Monomethyl Auristatin E (acMMAE) for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

AUCinf of acMMAE for pinatuzumab was estimated from plasma concentration data using non-compartmental analysis. Antibody conjugated MMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received pinatuzumab vedotin (Arm A) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 17 | | |
| Units: day*nanogram (ng)/mL | | | | |
| arithmetic mean (standard deviation) | 2840 (± 555) | 3110 (± 828) | | |

Statistical analyses

Secondary: Area Under the Concentration-Time Curve from Time Zero To Last Measurable Concentration (AUClast) of Unconjugated MMAE for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | Area Under the Concentration-Time Curve from Time Zero To Last Measurable Concentration (AUClast) of Unconjugated MMAE for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

AUClast of unconjugated MMAE was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received pinatuzumab vedotin (Arm A) with measurable PK concentrations.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm A (DLBCL): RTX+Pinatuzumab, Then RTX+Polatuzumab | Arm A (FL): RTX+Pinatuzumab, Then RTX+Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 21 | | |
| Units: day*ng/mL | | | | |
| arithmetic mean (standard deviation) | 34.2 (± 24.0) | 33.5 (± 17.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Total Antibody for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | Cmax of Total Antibody for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

Cmax of total antibody for pinatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with MMAE-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received pinatuzumab vedotin (Arm A) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 20 | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 42.5 (± 11.6) | 48.3 (± 9.34) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of acMMAE for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | Cmax of acMMAE for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

Cmax of acMMAE for pinatuzumab was estimated from plasma concentration data using non-compartmental analysis. acMMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received pinatuzumab vedotin (Arm A) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm A (DLBCL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | Arm A (FL): RTX+Pinatuzu mab,Then RTX+Polatuzu mab | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 38 | 21 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 850 (± 222) | 994 (± 190) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Unconjugated MMAE for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|---|
| End point title | Cmax of Unconjugated MMAE for Pinatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|---|

End point description:

Cmax of unconjugated MMAE was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received pinatuzumab vedotin (Arm A) with measurable PK concentrations.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm A (DLBCL): RTX+Pinatuzumab, Then RTX+Polatuzumab | Arm A (FL): RTX+Pinatuzumab, Then RTX+Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 21 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 4.39 (± 3.15) | 4.20 (± 2.32) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of Total Antibody for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUCinf of Total Antibody for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

AUCinf of total antibody for polatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with MMAE-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 2.4 mg/kg in combination with rituximab (Arm B) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm B (DLBCL): RTX+Polatuzumab, Then RTX+Pinatuzumab | Arm B (FL): RTX+Polatuzumab, Then RTX+Pinatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 26 | 17 | | |
| Units: day*mcg/mL | | | | |
| arithmetic mean (standard deviation) | 412 (± 108) | 428 (± 106) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of acMMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUCinf of acMMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

AUCinf of acMMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. acMMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 2.4 mg/kg in combination with rituximab (Arm B) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm B (DLBCL): RTX+Polatuzumab, Then RTX+Pinatuzumab | Arm B (FL): RTX+Polatuzumab, Then RTX+Pinatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 30 | 17 | | |
| Units: day*ng/mL | | | | |
| arithmetic mean (standard deviation) | 3660 (± 843) | 3510 (± 1160) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUClast of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

AUClast of Unconjugated MMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 2.4 mg/kg in combination with rituximab (Arm B) with measurable PK concentrations.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm B (DLBCL): RTX+Polatuzumab, Then RTX+Pinatuzumab | Arm B (FL): RTX+Polatuzumab, Then RTX+Pinatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 18 | | |
| Units: day*ng/mL | | | | |
| arithmetic mean (standard deviation) | 31.7 (± 17.2) | 29.5 (± 25.0) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Total Antibody for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | Cmax of Total Antibody for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

Cmax of total antibody for polatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with MMAE-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 2.4 mg/kg in combination with rituximab (Arm B) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm B (DLBCL): RTX+Polatuzumab, Then RTX+Pinatuzumab | Arm B (FL): RTX+Polatuzumab, Then RTX+Pinatuzumab | | |
|-----------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 38 | 16 | | |

| | | | | |
|--------------------------------------|---------------|---------------|--|--|
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 51.9 (± 12.3) | 55.9 (± 12.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of acMMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | Cmax of acMMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|--|

End point description:

Cmax of acMMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. acMMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 2.4 mg/kg in combination with rituximab (Arm B) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm B (DLBCL): RTX+Polatuzumab, Then RTX+Pinatuzumab | Arm B (FL): RTX+Polatuzumab, Then RTX+Pinatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 38 | 17 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 948 (± 204) | 968 (± 268) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab

| | |
|-----------------|---|
| End point title | Cmax of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 2.4 mg/kg Given in Combination with Rituximab |
|-----------------|---|

End point description:

Cmax of Unconjugated MMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 2.4 mg/kg in combination with rituximab (Arm B) with measurable PK concentrations.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Arm B (DLBCL): RTX+Polatuzumab, Then RTX+Pinatuzumab | Arm B (FL): RTX+Polatuzumab, Then RTX+Pinatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 39 | 18 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 3.72 (± 1.98) | 3.29 (± 2.71) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUCinf of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab ^[22] |
|-----------------|--|

End point description:

AUCinf of total antibody for polatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with MMAE-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with rituximab (Cohort C) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| End point values | Cohort C (FL): RTX + Polatuzumab | | | |
|--------------------------------------|----------------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: day*mcg/mL | | | | |
| arithmetic mean (standard deviation) | 258 (± 84.1) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUCinf of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab ^[23] |
|-----------------|--|

End point description:

AUCinf of acMMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. acMMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with rituximab (Cohort C) with measurable PK concentrations. Here, 'Number of Subjects Analyzed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| | | | | |
|--------------------------------------|----------------------------------|--|--|--|
| End point values | Cohort C (FL): RTX + Polatuzumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 15 | | | |
| Units: day*ng/mL | | | | |
| arithmetic mean (standard deviation) | 2600 (± 630) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | AUClast of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab ^[24] |
|-----------------|--|

End point description:

AUClast of Unconjugated MMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with rituximab (Cohort C) with measurable PK concentrations.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Cohort C (FL): RTX + Polatuzumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 20 | | | |
| Units: day*ng/mL | | | | |
| arithmetic mean (standard deviation) | 17.7 (± 9.39) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | Cmax of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab ^[25] |
|-----------------|--|

End point description:

Cmax of total antibody for polatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with MMAE-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with rituximab (Cohort C) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Cohort C (FL): RTX + Polatuzumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 19 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 42.2 (± 7.92) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab

| | |
|-----------------|--|
| End point title | Cmax of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab ^[26] |
|-----------------|--|

End point description:

Cmax of acMMAE for polatuzumab vedotin was estimated from plasma concentration data using non-

compartmental analysis. acMMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with rituximab (Cohort C) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days) | |

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| | | | | |
|--------------------------------------|----------------------------------|--|--|--|
| End point values | Cohort C (FL): RTX + Polatuzumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 787 (\pm 113) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab

| | |
|-----------------|---|
| End point title | Cmax of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Rituximab ^[27] |
|-----------------|---|

End point description:

Cmax of Unconjugated MMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with rituximab (Cohort C) with measurable PK concentrations.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days) | |

Notes:

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

Justification: Reported analysis was planned to be carried out in the indicated arms only.

| | | | | |
|--------------------------------------|----------------------------------|--|--|--|
| End point values | Cohort C (FL): RTX + Polatuzumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 20 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 2.02 (\pm 1.34) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab

| | |
|-----------------|---|
| End point title | AUCinf of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab |
|-----------------|---|

End point description:

AUCinf of total antibody for polatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with MMAE-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with obinutuzumab (Cohort E+H and E+G) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 30 | 27 | | |
| Units: day*mcg/mL | | | | |
| arithmetic mean (standard deviation) | 215 (± 102) | 218 (± 89.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab

| | |
|-----------------|---|
| End point title | AUCinf of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab |
|-----------------|---|

End point description:

AUCinf of acMMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. acMMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with obinutuzumab (Cohort E+H and E+G) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days) | |

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 29 | 26 | | |
| Units: day*ng/mL | | | | |
| arithmetic mean (standard deviation) | 2340 (± 875) | 2440 (± 665) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab

| | |
|-----------------|---|
| End point title | AUClast of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab |
|-----------------|---|

End point description:

AUClast of Unconjugated MMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with obinutuzumab (Cohort E+H and E+G) with measurable PK concentrations.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days) | |

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 41 | 40 | | |
| Units: day*ng/mL | | | | |
| arithmetic mean (standard deviation) | 22.3 (± 9.46) | 27.9 (± 21.3) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab

| | |
|-----------------|---|
| End point title | Cmax of Total Antibody for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab |
|-----------------|---|

End point description:

Cmax of total antibody for polatuzumab vedotin was estimated from serum concentration data using non-compartmental analysis. Total antibody is defined as antibody with MMAE-to-antibody ratio equal or greater than zero, including fully conjugated, partially unconjugated, and fully unconjugated antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with obinutuzumab (Cohort E+H and E+G) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 38 | 37 | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 34.2 (± 7.89) | 35.0 (± 9.89) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab

| | |
|-----------------|---|
| End point title | Cmax of acMMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab |
|-----------------|---|

End point description:

Cmax of acMMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. acMMAE is the total concentration of MMAE that was conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with obinutuzumab (Cohort E+H and E+G) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 33 | 33 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 694 (± 161) | 711 (± 155) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab

| | |
|---|--|
| End point title | Cmax of Unconjugated MMAE for Polatuzumab Vedotin at Dose Level 1.8 mg/kg Given in Combination with Obinutuzumab |
| End point description: | |
| Cmax of Unconjugated MMAE for polatuzumab vedotin was estimated from plasma concentration data using non-compartmental analysis. Unconjugated MMAE is the total concentration of MMAE that was not conjugated to the antibody. Analysis was performed on all participants who received polatuzumab vedotin at dose level 1.8 mg/kg in combination with obinutuzumab (Cohort E+H and E+G) with measurable PK concentrations. | |
| End point type | Secondary |
| End point timeframe: | |
| Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days) | |

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 41 | 40 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 2.80 (± 1.30) | 3.62 (± 3.73) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Obinutuzumab: Obinutuzumab-Containing Cohorts (Cohorts E +

H and E + G)

| | |
|-----------------|---|
| End point title | Cmax of Obinutuzumab: Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G) |
|-----------------|---|

End point description:

Cmax of obinutuzumab was estimated from serum concentration data using non-compartmental analysis. Analysis was performed on all participants who received obinutuzumab (Cohort E+H and E+G) with measurable PK concentrations. Here, 'Number of Subjects Analysed' signifies the number of participants evaluable for this outcome measure.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-infusion (Hour 0) & 30 minutes Post-infusion (infusion length=30-90 minutes) on Day 1 of Cycle 1; Day 8, Day 15 of Cycle 1 (Cycle length= 21 Days)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 35 | 40 | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 330 (± 87.9) | 340 (± 95.0) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS): Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G)

| | |
|-----------------|--|
| End point title | Overall Survival (OS): Obinutuzumab-Containing Cohorts (Cohorts E + H and E + G) |
|-----------------|--|

End point description:

OS was defined as the time from the date of randomization or enrollment to the date of death from any cause. The median OS was estimated using Kaplan-Meier estimates and the 95% CI for median was computed using the method of Brookmeyer and Crowley.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to death due to any cause (from baseline up to study completion date, up to approximately 5.5 years)

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 9 | 35 | | |
| Units: Months | | | | |

| | | | | |
|----------------------------------|---------------------|--------------------|--|--|
| median (confidence interval 95%) | 99.9 (38.4 to 99.9) | 10.5 (5.5 to 16.7) | | |
|----------------------------------|---------------------|--------------------|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Died due to any Cause: Obinutuzumab Containing Cohorts (Cohorts E + H and E + G)

| | |
|------------------------|--|
| End point title | Percentage of Participants who Died due to any Cause: Obinutuzumab Containing Cohorts (Cohorts E + H and E + G) |
| End point description: | Percentage of participants who died due to any cause was reported. |
| End point type | Secondary |
| End point timeframe: | Baseline up to death due to any cause (from baseline up to study completion date, up to approximately 5.5 years) |

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 44 | 45 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 20.5 | 77.8 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) as Determined by Modified Response and Progression Criteria for NHL: Obinutuzumab Containing Cohorts (Cohorts E + H and E + G)

| | |
|------------------------|--|
| End point title | Progression-free Survival (PFS) as Determined by Modified Response and Progression Criteria for NHL: Obinutuzumab Containing Cohorts (Cohorts E + H and E + G) |
| End point description: | <p>Tumor response was evaluated according to modified response and progression criteria for NHL published by Cheson et al (2007 and 2014) and confirmed by repeat assessments ≥ 4 weeks after initial documentation. PD was defined as appearance of any new lesion more than 1.5 cm in any axis, at least a 50% increase from nadir in the SPD or longest diameter of any previous lesion or node. PFS was defined as the time from the date of randomization to the date of PD or death from any cause, whichever occurred first. In absence of PD or death, PFS was censored at the date of the last tumor assessment. Participants with no post-baseline tumor assessment were censored on the date of randomization or date of enrollment. The median PFS was estimated using Kaplan-Meier estimates and the 95% CI for median was computed using the method of Brookmeyer and Crowley.</p> |

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 5.5 years) | |

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|----------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 44 | 45 | | |
| Units: months | | | | |
| median (confidence interval 95%) | 19.5 (10.9 to 38.4) | 2.7 (2.1 to 5.9) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with PD as Determined by Modified Response and Progression Criteria for NHL or Death due to any Cause: Obinutuzumab Containing Cohorts (Cohorts E + H and E + G)

| | |
|-----------------|---|
| End point title | Percentage of Participants with PD as Determined by Modified Response and Progression Criteria for NHL or Death due to any Cause: Obinutuzumab Containing Cohorts (Cohorts E + H and E + G) |
|-----------------|---|

End point description:

Tumor response was evaluated according to modified response and progression criteria for NHL published by Cheson et al (2007 and 2014) and confirmed by repeat assessments ≥ 4 weeks after initial documentation. PD was defined as appearance of any new lesion more than 1.5 cm in any axis, at least a 50% increase from nadir in the SPD or longest diameter of any previous lesion or node.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline up to PD or death due to any cause, whichever occurs first (up to approximately 5.5 years) | |

| End point values | Cohort E + Cohort G (FL): Obinutuzumab + Polatuzumab | Cohort E + Cohort H (DLBCL): Obinutuzumab + Polatuzumab | | |
|-----------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 44 | 45 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 56.8 | 88.9 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 30 days after the last dose of study treatment (up to approximately 12 months for rituximab-containing regimens [Arms A and B, Cohort C] and 24 weeks for Cohorts E, G, and H)

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 22.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Arm A (FL+DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab |
|-----------------------|--|

Reporting group description:

Participants with relapsed or refractory [r/r] FL and DLBCL received rituximab (RTX) at a dose of 375 milligrams per square meter (mg/m²) administered via intravenous (IV) infusion on Day 1 and pinatuzumab vedotin at a dose of 2.4 milligrams per kilogram (mg/kg) administered via IV infusion on Day 2 for the first 2 cycles. RTX and pinatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed disease progression (PD) were treated with RTX at 375 mg/m² and polatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
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| Reporting group title | Arm B (FL+DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab |
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Reporting group description:

Participants with r/r FL and DLBCL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 2.4 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle, in the absence of any infusion-related adverse events. Participants who developed PD were treated with RTX at 375 mg/m² and pinatuzumab vedotin at 2.4 mg/kg via IV infusion on Day 1, beginning no later than 42 days after the last dose of the prior study treatment until a second PD event, clinical deterioration, and/or intolerance to the crossover treatment for up to a maximum of 1 year (maximum 17 cycles on an every-21-day schedule).

| | |
|-----------------------|----------------------------------|
| Reporting group title | Cohort C (FL): RTX + Polatuzumab |
|-----------------------|----------------------------------|

Reporting group description:

Participants with r/r FL received RTX at a dose of 375 mg/m² administered via IV infusion on Day 1 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first 2 cycles. In the absence of any infusion-related adverse events, RTX and polatuzumab were administered on the same day (Day 1) in subsequent cycles beginning with the third cycle for up to a maximum of 1 year (17 cycles on an every-21-day schedule) or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|---|
| Reporting group title | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab |
|-----------------------|---|

Reporting group description:

Participants with r/r FL and DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|--|
| Reporting group title | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab |
|-----------------------|--|

Reporting group description:

Participants with r/r FL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8, 15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| | |
|-----------------------|---|
| Reporting group title | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|-----------------------|---|

Reporting group description:

Participants with r/r DLBCL received obinutuzumab at a dose of 1000 mg via IV infusion on Days 1, 8,

15 and polatuzumab vedotin at a dose of 1.8 mg/kg administered via IV infusion on Day 2 for the first cycle. In the absence of any infusion-related adverse events, obinutuzumab and polatuzumab vedotin were administered on the same day (Day 1) in subsequent cycles beginning with the second cycle for up to a maximum of 8 cycles or significant toxicity, disease progression, or withdrawal from study.

| Serious adverse events | Arm A (FL+DLBCL): RTX+Pinatuzumab, then RTX+Polatuzumab | Arm B (FL+DLBCL): RTX+Polatuzumab, then RTX+Pinatuzumab | Cohort C (FL): RTX + Polatuzumab |
|---|---|---|-------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 27 / 63 (42.86%) | 21 / 59 (35.59%) | 8 / 20 (40.00%) |
| number of deaths (all causes) | 35 | 33 | 6 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Ganglioneuroma | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest discomfort | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sudden death | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 63 (1.59%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung disorder | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary congestion | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Bronchiectasis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural Haematoma | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wound secretion | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial flutter | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral motor neuropathy | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic Encephalopathy | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Blood and lymphatic system disorders | | | |
| Coagulopathy | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 2 / 59 (3.39%) | 2 / 20 (10.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 3 / 3 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colonic fistula | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fistula of small intestine | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric perforation | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hernial eventration | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subileus | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Duodenal perforation | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Bile duct obstruction | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis acute | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatomegaly | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver Disorder | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 2 / 59 (3.39%) | 0 / 20 (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 |
| Chronic kidney disease | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary retention | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Bone pain | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridial sepsis | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Device related infection | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Febrile infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urosepsis | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Viral diarrhoea | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Cachexia | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour lysis syndrome | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|---|--|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | 9 / 40 (22.50%) | 18 / 40 (45.00%) |
| number of deaths (all causes) | 4 | 8 | 32 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Ganglioneuroma | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest discomfort | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (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 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (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 physical health deterioration | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sudden death | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung disorder | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary congestion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiectasis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 0 / 40 (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 |
| Subdural Haematoma | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (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 |
| Wound secretion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial flutter | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral motor neuropathy | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic Encephalopathy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 | | | |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colonic fistula | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fistula of small intestine | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric perforation | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 0 / 40 (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 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hernial eventration | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subileus | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Duodenal perforation | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Bile duct obstruction | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (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 |
| Cholecystitis acute | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatomegaly | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver Disorder | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic kidney disease | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Bone pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (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 |
| Clostridial sepsis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Device related infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 0 / 40 (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 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 / 9 (0.00%) | 2 / 40 (5.00%) | 2 / 40 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral diarrhoea | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| 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 | | | |
| Cachexia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour lysis syndrome | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (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 |

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

| Non-serious adverse events | Arm A (FL+DLBCL): RTX+Pinatuzumab,T hen RTX+Polatuzumab | Arm B (FL+DLBCL): RTX+Polatuzumab,T hen RTX+Pinatuzumab | Cohort C (FL): RTX + Polatuzumab |
|---|--|--|-------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 63 / 63 (100.00%) | 58 / 59 (98.31%) | 20 / 20 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign neoplasm of skin | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 5 |
| Vascular disorders | | | |
| Flushing | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematoma | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 3 / 59 (5.08%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 4 / 63 (6.35%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 4 | 1 | 1 |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Surgical and medical procedures | | | |

| | | | |
|--|------------------------|------------------------|------------------------|
| Thrombolysis subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| General disorders and administration site conditions | | | |
| Asthenia subjects affected / exposed occurrences (all) | 11 / 63 (17.46%) 14 | 16 / 59 (27.12%) 26 | 0 / 20 (0.00%) 0 |
| Chest pain subjects affected / exposed occurrences (all) | 4 / 63 (6.35%) 5 | 6 / 59 (10.17%) 7 | 2 / 20 (10.00%) 2 |
| Chills subjects affected / exposed occurrences (all) | 5 / 63 (7.94%) 7 | 4 / 59 (6.78%) 6 | 3 / 20 (15.00%) 6 |
| Fatigue subjects affected / exposed occurrences (all) | 32 / 63 (50.79%) 49 | 34 / 59 (57.63%) 51 | 13 / 20 (65.00%) 19 |
| Feeling hot subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Gait disturbance subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 3 / 59 (5.08%) 4 | 1 / 20 (5.00%) 2 |
| Influenza like illness subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 8 / 59 (13.56%) 14 | 0 / 20 (0.00%) 0 |
| Malaise subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 2 / 59 (3.39%) 3 | 1 / 20 (5.00%) 1 |
| Nodule subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Oedema peripheral subjects affected / exposed occurrences (all) | 6 / 63 (9.52%) 8 | 8 / 59 (13.56%) 11 | 3 / 20 (15.00%) 4 |
| Pain | | | |

| | | | |
|--|------------------------|------------------------|-----------------------|
| subjects affected / exposed occurrences (all) | 5 / 63 (7.94%) 5 | 1 / 59 (1.69%) 2 | 3 / 20 (15.00%) 4 |
| Peripheral swelling subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 2 / 59 (3.39%) 2 | 0 / 20 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 15 / 63 (23.81%) 19 | 9 / 59 (15.25%) 12 | 5 / 20 (25.00%) 20 |
| Unevaluable event subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Immune system disorders Hypogammaglobulinaemia subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 9 / 63 (14.29%) 10 | 15 / 59 (25.42%) 16 | 3 / 20 (15.00%) 6 |
| Dysphonia subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 2 / 59 (3.39%) 2 | 1 / 20 (5.00%) 1 |
| Dyspnoea subjects affected / exposed occurrences (all) | 11 / 63 (17.46%) 13 | 11 / 59 (18.64%) 14 | 2 / 20 (10.00%) 4 |
| Dyspnoea exertional subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 0 / 59 (0.00%) 0 | 2 / 20 (10.00%) 2 |
| Epistaxis subjects affected / exposed occurrences (all) | 3 / 63 (4.76%) 3 | 1 / 59 (1.69%) 1 | 2 / 20 (10.00%) 2 |
| Hiccups | | | |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 4 / 63 (6.35%) | 2 / 59 (3.39%) | 2 / 20 (10.00%) |
| occurrences (all) | 4 | 2 | 3 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 6 / 63 (9.52%) | 0 / 59 (0.00%) | 3 / 20 (15.00%) |
| occurrences (all) | 7 | 0 | 3 |
| Orthopnoea | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pleural effusion | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 0 / 59 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 2 | 0 | 3 |
| Productive cough | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 3 / 59 (5.08%) | 4 / 20 (20.00%) |
| occurrences (all) | 1 | 3 | 5 |
| Pulmonary congestion | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 0 / 59 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 3 | 0 | 2 |
| Sinus congestion | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Sneezing | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchiectasis | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Psychiatric disorders | | | |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Anxiety | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 5 / 59 (8.47%) | 1 / 20 (5.00%) |
| occurrences (all) | 2 | 6 | 1 |
| Depression | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 4 / 59 (6.78%) | 1 / 20 (5.00%) |
| occurrences (all) | 4 | 4 | 1 |
| Hallucination olfactory | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Insomnia | | | |
| subjects affected / exposed | 15 / 63 (23.81%) | 8 / 59 (13.56%) | 3 / 20 (15.00%) |
| occurrences (all) | 16 | 12 | 3 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 2 / 59 (3.39%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 9 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Blood potassium decreased | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |

| | | | |
|--|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 4 / 59 (6.78%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 6 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Protein total decreased | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 6 / 63 (9.52%) | 7 / 59 (11.86%) | 3 / 20 (15.00%) |
| occurrences (all) | 9 | 7 | 4 |
| Weight increased | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 1 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 4 / 59 (6.78%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 7 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Contusion | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Fall | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 2 / 59 (3.39%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 1 / 59 (1.69%) | 2 / 20 (10.00%) |
| occurrences (all) | 5 | 1 | 3 |
| Procedural pain | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Radiation skin injury | | | |

| | | | |
|-----------------------------|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Skin Abrasion | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Cardiac tamponade | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Tachycardia | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 3 / 59 (5.08%) | 0 / 20 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Nervous system disorders | | | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Cluster headache | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Cognitive disorder | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Cubital tunnel syndrome | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dizziness | | | |
| subjects affected / exposed | 7 / 63 (11.11%) | 10 / 59 (16.95%) | 3 / 20 (15.00%) |
| occurrences (all) | 7 | 13 | 5 |
| Dysgeusia | | | |

| | | | |
|-------------------------------|------------------|------------------|------------------|
| subjects affected / exposed | 2 / 63 (3.17%) | 3 / 59 (5.08%) | 1 / 20 (5.00%) |
| occurrences (all) | 2 | 3 | 1 |
| Headache | | | |
| subjects affected / exposed | 10 / 63 (15.87%) | 8 / 59 (13.56%) | 6 / 20 (30.00%) |
| occurrences (all) | 15 | 14 | 7 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 2 / 59 (3.39%) | 2 / 20 (10.00%) |
| occurrences (all) | 3 | 3 | 2 |
| Memory impairment | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 3 / 59 (5.08%) | 2 / 20 (10.00%) |
| occurrences (all) | 1 | 3 | 2 |
| Nerve compression | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 23 / 63 (36.51%) | 27 / 59 (45.76%) | 6 / 20 (30.00%) |
| occurrences (all) | 46 | 40 | 15 |
| Paraesthesia | | | |
| subjects affected / exposed | 5 / 63 (7.94%) | 1 / 59 (1.69%) | 2 / 20 (10.00%) |
| occurrences (all) | 6 | 8 | 2 |
| Peripheral motor neuropathy | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 5 / 59 (8.47%) | 1 / 20 (5.00%) |
| occurrences (all) | 2 | 6 | 3 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 16 / 63 (25.40%) | 17 / 59 (28.81%) | 11 / 20 (55.00%) |
| occurrences (all) | 21 | 30 | 22 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Hepatic Encephalopathy | | | |

| | | | |
|--|------------------------|------------------------|-----------------------|
| subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Taste Disorder subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 3 / 59 (5.08%) 3 | 0 / 20 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 9 / 63 (14.29%) 9 | 10 / 59 (16.95%) 12 | 1 / 20 (5.00%) 1 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 1 / 59 (1.69%) 1 | 1 / 20 (5.00%) 1 |
| Neutropenia subjects affected / exposed occurrences (all) | 19 / 63 (30.16%) 49 | 15 / 59 (25.42%) 31 | 8 / 20 (40.00%) 16 |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 3 / 63 (4.76%) 9 | 2 / 59 (3.39%) 3 | 0 / 20 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| Ear discomfort subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 1 / 59 (1.69%) 1 | 1 / 20 (5.00%) 1 |
| Ear pain subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Vertigo subjects affected / exposed occurrences (all) | 2 / 63 (3.17%) 2 | 1 / 59 (1.69%) 1 | 1 / 20 (5.00%) 1 |
| Eye disorders | | | |
| Dry eye subjects affected / exposed occurrences (all) | 2 / 63 (3.17%) 3 | 0 / 59 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Eye pain subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Lacrimation increased | | | |

| | | | |
|--|------------------------|------------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 0 / 59 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| Vision blurred subjects affected / exposed occurrences (all) | 6 / 63 (9.52%) 11 | 2 / 59 (3.39%) 2 | 2 / 20 (10.00%) 2 |
| Visual impairment subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 2 | 1 / 59 (1.69%) 1 | 0 / 20 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 2 / 63 (3.17%) 2 | 3 / 59 (5.08%) 3 | 1 / 20 (5.00%) 1 |
| Abdominal distension subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 2 / 59 (3.39%) 2 | 0 / 20 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 11 / 63 (17.46%) 15 | 11 / 59 (18.64%) 15 | 2 / 20 (10.00%) 2 |
| Abdominal pain lower subjects affected / exposed occurrences (all) | 2 / 63 (3.17%) 2 | 1 / 59 (1.69%) 1 | 1 / 20 (5.00%) 1 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 1 | 4 / 59 (6.78%) 4 | 2 / 20 (10.00%) 2 |
| Constipation subjects affected / exposed occurrences (all) | 18 / 63 (28.57%) 21 | 14 / 59 (23.73%) 18 | 5 / 20 (25.00%) 6 |
| Diarrhoea subjects affected / exposed occurrences (all) | 28 / 63 (44.44%) 42 | 25 / 59 (42.37%) 43 | 5 / 20 (25.00%) 7 |
| Dry mouth subjects affected / exposed occurrences (all) | 5 / 63 (7.94%) 5 | 5 / 59 (8.47%) 6 | 1 / 20 (5.00%) 1 |
| Dyspepsia subjects affected / exposed occurrences (all) | 4 / 63 (6.35%) 4 | 8 / 59 (13.56%) 9 | 3 / 20 (15.00%) 3 |

| | | | |
|--|------------------|------------------|------------------|
| Dysphagia | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 4 / 63 (6.35%) | 0 / 59 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 5 | 0 | 2 |
| Haemorrhoids | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 2 | 0 | 1 |
| Nausea | | | |
| subjects affected / exposed | 20 / 63 (31.75%) | 25 / 59 (42.37%) | 11 / 20 (55.00%) |
| occurrences (all) | 27 | 37 | 14 |
| Toothache | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 2 / 59 (3.39%) | 2 / 20 (10.00%) |
| occurrences (all) | 0 | 2 | 2 |
| Vomiting | | | |
| subjects affected / exposed | 11 / 63 (17.46%) | 13 / 59 (22.03%) | 3 / 20 (15.00%) |
| occurrences (all) | 13 | 17 | 8 |
| Hepatobiliary disorders | | | |
| Liver Disorder | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Actinic keratosis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Alopecia | | | |

| | | | |
|-----------------------------|------------------|-----------------|-----------------|
| subjects affected / exposed | 10 / 63 (15.87%) | 7 / 59 (11.86%) | 1 / 20 (5.00%) |
| occurrences (all) | 11 | 7 | 1 |
| Brow ptosis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Dry skin | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 4 / 63 (6.35%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 4 | 1 | 5 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 4 / 59 (6.78%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 5 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 6 / 63 (9.52%) | 4 / 59 (6.78%) | 3 / 20 (15.00%) |
| occurrences (all) | 9 | 5 | 4 |
| Pruritus | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 6 / 59 (10.17%) | 2 / 20 (10.00%) |
| occurrences (all) | 4 | 7 | 2 |
| Rash | | | |
| subjects affected / exposed | 3 / 63 (4.76%) | 3 / 59 (5.08%) | 0 / 20 (0.00%) |
| occurrences (all) | 4 | 5 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Rash pruritic | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 2 | 1 | 1 |
| Renal and urinary disorders | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| Dysuria | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 3 / 59 (5.08%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 4 | 1 |
| Nocturia | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary hesitation | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 9 / 63 (14.29%) | 11 / 59 (18.64%) | 5 / 20 (25.00%) |
| occurrences (all) | 12 | 13 | 7 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Back pain | | | |
| subjects affected / exposed | 7 / 63 (11.11%) | 8 / 59 (13.56%) | 3 / 20 (15.00%) |
| occurrences (all) | 8 | 13 | 3 |
| Bone pain | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 6 / 59 (10.17%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 16 | 2 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Joint stiffness | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Muscle spasms | | | |
| subjects affected / exposed | 5 / 63 (7.94%) | 6 / 59 (10.17%) | 2 / 20 (10.00%) |
| occurrences (all) | 8 | 6 | 2 |
| Muscle tightness | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Muscular weakness | | | |

| | | | |
|-----------------------------|-----------------|------------------|-----------------|
| subjects affected / exposed | 2 / 63 (3.17%) | 6 / 59 (10.17%) | 0 / 20 (0.00%) |
| occurrences (all) | 4 | 9 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 4 / 63 (6.35%) | 5 / 59 (8.47%) | 2 / 20 (10.00%) |
| occurrences (all) | 4 | 8 | 3 |
| Myalgia | | | |
| subjects affected / exposed | 7 / 63 (11.11%) | 6 / 59 (10.17%) | 3 / 20 (15.00%) |
| occurrences (all) | 8 | 12 | 3 |
| Osteopenia | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain in extremity | | | |
| subjects affected / exposed | 7 / 63 (11.11%) | 12 / 59 (20.34%) | 4 / 20 (20.00%) |
| occurrences (all) | 12 | 21 | 5 |
| Infections and infestations | | | |
| Candida infection | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| Influenza | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Oesophageal candidiasis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Oral candidiasis | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 2 / 59 (3.39%) | 1 / 20 (5.00%) |
| occurrences (all) | 2 | 2 | 1 |
| Oropharyngeal candidiasis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Pilonidal cyst | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 63 (1.59%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 1 / 59 (1.69%) | 2 / 20 (10.00%) |
| occurrences (all) | 0 | 2 | 2 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|------------------------|------------------------|-----------------------|
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 5 / 63 (7.94%) 5 | 2 / 59 (3.39%) 2 | 3 / 20 (15.00%) 3 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 6 / 63 (9.52%) 6 | 2 / 59 (3.39%) 2 | 0 / 20 (0.00%) 0 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 2 / 63 (3.17%) 2 | 1 / 59 (1.69%) 3 | 4 / 20 (20.00%) 4 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite subjects affected / exposed occurrences (all) | 13 / 63 (20.63%) 19 | 17 / 59 (28.81%) 18 | 4 / 20 (20.00%) 10 |
| Dehydration subjects affected / exposed occurrences (all) | 6 / 63 (9.52%) 7 | 3 / 59 (5.08%) 3 | 2 / 20 (10.00%) 2 |
| Gout subjects affected / exposed occurrences (all) | 0 / 63 (0.00%) 0 | 1 / 59 (1.69%) 1 | 1 / 20 (5.00%) 4 |
| Hypercalcaemia subjects affected / exposed occurrences (all) | 1 / 63 (1.59%) 2 | 1 / 59 (1.69%) 1 | 0 / 20 (0.00%) 0 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 8 / 63 (12.70%) 10 | 4 / 59 (6.78%) 9 | 2 / 20 (10.00%) 2 |
| Hyperuricaemia subjects affected / exposed occurrences (all) | 2 / 63 (3.17%) 2 | 1 / 59 (1.69%) 1 | 0 / 20 (0.00%) 0 |
| Hypokalaemia subjects affected / exposed occurrences (all) | 7 / 63 (11.11%) 11 | 8 / 59 (13.56%) 13 | 0 / 20 (0.00%) 0 |
| Hypomagnesaemia subjects affected / exposed occurrences (all) | 5 / 63 (7.94%) 6 | 6 / 59 (10.17%) 6 | 1 / 20 (5.00%) 1 |
| Hyponatraemia | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 63 (1.59%) | 2 / 59 (3.39%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 3 | 1 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 2 / 63 (3.17%) | 3 / 59 (5.08%) | 1 / 20 (5.00%) |
| occurrences (all) | 2 | 4 | 1 |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 63 (0.00%) | 0 / 59 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |

| Non-serious adverse events | Cohort E (FL+DLBCL): Obinutuzumab + Polatuzumab | Cohort G (Expansion, FL): Obinutuzumab + Polatuzumab | Cohort H (Expansion, DLBCL): Obinutuzumab + Polatuzumab |
|---|--|---|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 9 / 9 (100.00%) | 37 / 40 (92.50%) | 38 / 40 (95.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign neoplasm of skin | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Flushing | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 4 / 40 (10.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 5 | 1 |
| Haematoma | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 4 / 40 (10.00%) |
| occurrences (all) | 0 | 2 | 5 |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------|------------------|-----------------|
| Surgical and medical procedures | | | |
| Thrombolysis | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 3 / 40 (7.50%) | 8 / 40 (20.00%) |
| occurrences (all) | 1 | 4 | 9 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Chills | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 8 / 40 (20.00%) | 5 / 40 (12.50%) |
| occurrences (all) | 0 | 9 | 6 |
| Fatigue | | | |
| subjects affected / exposed | 5 / 9 (55.56%) | 18 / 40 (45.00%) | 9 / 40 (22.50%) |
| occurrences (all) | 5 | 24 | 9 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 2 | 3 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 2 | 1 |
| Nodule | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 3 / 40 (7.50%) |
| occurrences (all) | 0 | 3 | 4 |
| Pain | | | |

| | | | |
|--|---------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 40 (2.50%) 1 |
| Peripheral swelling subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 2 | 0 / 40 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 2 / 9 (22.22%) 2 | 5 / 40 (12.50%) 5 | 3 / 40 (7.50%) 3 |
| Unevaluable event subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Immune system disorders Hypogammaglobulinaemia subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 |
| Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 7 / 40 (17.50%) 7 | 6 / 40 (15.00%) 7 |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 3 | 2 / 40 (5.00%) 2 |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 5 / 40 (12.50%) 5 | 8 / 40 (20.00%) 9 |
| Dyspnoea exertional subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 40 (2.50%) 1 | 1 / 40 (2.50%) 2 |
| Epistaxis subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 40 (2.50%) 2 | 2 / 40 (5.00%) 2 |
| Hiccups | | | |

| | | | |
|-----------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 2 | 2 |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 4 / 40 (10.00%) | 3 / 40 (7.50%) |
| occurrences (all) | 1 | 4 | 3 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 2 / 40 (5.00%) | 3 / 40 (7.50%) |
| occurrences (all) | 1 | 2 | 3 |
| Orthopnoea | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Productive cough | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | 4 / 40 (10.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 2 | 4 | 2 |
| Pulmonary congestion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | 1 / 40 (2.50%) | 2 / 40 (5.00%) |
| occurrences (all) | 2 | 1 | 2 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sneezing | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchiectasis | | | |

| | | | |
|--|---------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Psychiatric disorders | | | |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Anxiety | | | |
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 2 | 1 / 40 (2.50%) 1 |
| Depression | | | |
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 40 (2.50%) 1 | 1 / 40 (2.50%) 1 |
| Hallucination olfactory | | | |
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Insomnia | | | |
| subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 1 / 40 (2.50%) 1 | 6 / 40 (15.00%) 6 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 3 / 40 (7.50%) 3 | 1 / 40 (2.50%) 1 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 4 / 40 (10.00%) 5 | 2 / 40 (5.00%) 2 |
| Blood creatinine increased | | | |
| subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 1 / 40 (2.50%) 1 | 1 / 40 (2.50%) 3 |
| Blood potassium decreased | | | |
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Lipase increased | | | |
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 3 | 1 / 40 (2.50%) 1 |
| Neutrophil count decreased | | | |

| | | | |
|--|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 1 | 0 | 3 |
| Protein total decreased | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 2 / 40 (5.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 1 | 4 | 1 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Fall | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 3 / 40 (7.50%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 3 | 2 |
| Infusion related reaction | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 7 / 40 (17.50%) | 3 / 40 (7.50%) |
| occurrences (all) | 1 | 8 | 3 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Radiation skin injury | | | |

| | | | |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin Abrasion | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 40 (2.50%) | 2 / 40 (5.00%) |
| occurrences (all) | 1 | 1 | 3 |
| Cardiac tamponade | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Nervous system disorders | | | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cluster headache | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cognitive disorder | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cubital tunnel syndrome | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 6 / 40 (15.00%) | 4 / 40 (10.00%) |
| occurrences (all) | 0 | 7 | 4 |
| Dysgeusia | | | |

| | | | |
|-------------------------------|----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 3 / 40 (7.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 10 / 40 (25.00%) | 6 / 40 (15.00%) |
| occurrences (all) | 1 | 10 | 6 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 1 | 2 |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nerve compression | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 8 / 40 (20.00%) | 8 / 40 (20.00%) |
| occurrences (all) | 1 | 13 | 9 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 4 / 40 (10.00%) | 3 / 40 (7.50%) |
| occurrences (all) | 0 | 7 | 4 |
| Peripheral motor neuropathy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 4 / 40 (10.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | 7 / 40 (17.50%) | 2 / 40 (5.00%) |
| occurrences (all) | 3 | 10 | 5 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 3 / 40 (7.50%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 5 | 1 |
| Syncope | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 2 | 1 |
| Hepatic Encephalopathy | | | |

| | | | |
|--|---------------------|-----------------------|-----------------------|
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Taste Disorder subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 40 (2.50%) 1 | 1 / 40 (2.50%) 1 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 2 / 9 (22.22%) 2 | 4 / 40 (10.00%) 4 | 4 / 40 (10.00%) 4 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 2 | 0 / 40 (0.00%) 0 |
| Neutropenia subjects affected / exposed occurrences (all) | 4 / 9 (44.44%) 7 | 8 / 40 (20.00%) 12 | 8 / 40 (20.00%) 16 |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 4 / 40 (10.00%) 5 | 4 / 40 (10.00%) 8 |
| Ear and labyrinth disorders | | | |
| Ear discomfort subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 40 (2.50%) 1 |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 4 | 0 / 40 (0.00%) 0 |
| Eye disorders | | | |
| Dry eye subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 3 / 40 (7.50%) 3 | 0 / 40 (0.00%) 0 |
| Eye pain subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Lacrimation increased | | | |

| | | | |
|--|---------------------|------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 3 | 1 / 40 (2.50%) 1 |
| Visual impairment subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 2 | 0 / 40 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 40 (2.50%) 1 | 1 / 40 (2.50%) 1 |
| Abdominal distension subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 3 / 40 (7.50%) 4 | 4 / 40 (10.00%) 4 |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 4 / 40 (10.00%) 4 | 3 / 40 (7.50%) 6 |
| Abdominal pain lower subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 5 / 40 (12.50%) 5 | 4 / 40 (10.00%) 4 |
| Constipation subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 14 / 40 (35.00%) 14 | 8 / 40 (20.00%) 8 |
| Diarrhoea subjects affected / exposed occurrences (all) | 3 / 9 (33.33%) 3 | 13 / 40 (32.50%) 17 | 14 / 40 (35.00%) 23 |
| Dry mouth subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 2 | 1 / 40 (2.50%) 1 |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 5 / 40 (12.50%) 5 | 3 / 40 (7.50%) 3 |

| | | | |
|--|---------------|------------------|------------------|
| Dysphagia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 11 / 40 (27.50%) | 14 / 40 (35.00%) |
| occurrences (all) | 0 | 14 | 15 |
| Toothache | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 8 / 40 (20.00%) | 5 / 40 (12.50%) |
| occurrences (all) | 0 | 8 | 5 |
| Hepatobiliary disorders | | | |
| Liver Disorder | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Actinic keratosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |

| | | | |
|-----------------------------|---------------|-----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 2 | 1 |
| Brow ptosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 3 / 40 (7.50%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 3 | 2 |
| Erythema | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 3 / 40 (7.50%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 3 | 1 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 6 / 40 (15.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 7 | 1 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 7 / 40 (17.50%) | 3 / 40 (7.50%) |
| occurrences (all) | 0 | 9 | 3 |
| Rash | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Renal and urinary disorders | | | |

| | | | |
|---|----------------|-----------------|-----------------|
| Dysuria | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nocturia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Urinary hesitation | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 4 / 40 (10.00%) | 3 / 40 (7.50%) |
| occurrences (all) | 2 | 5 | 3 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 5 / 40 (12.50%) |
| occurrences (all) | 0 | 2 | 5 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint stiffness | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 3 / 40 (7.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Muscle tightness | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscular weakness | | | |

| | | | |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Osteopenia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 7 / 40 (17.50%) | 6 / 40 (15.00%) |
| occurrences (all) | 1 | 10 | 8 |
| Infections and infestations | | | |
| Candida infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Ear infection | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 1 | 3 |
| Infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Influenza | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 40 (2.50%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal candidiasis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Oropharyngeal candidiasis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pilonidal cyst | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | 2 / 40 (5.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 5 | 3 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 2 / 40 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |

| | | | |
|---|---------------------|----------------------|----------------------|
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 1 / 40 (2.50%) 1 | 0 / 40 (0.00%) 0 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 3 / 40 (7.50%) 3 | 1 / 40 (2.50%) 1 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 7 / 40 (17.50%) 7 | 5 / 40 (12.50%) 5 |
| Dehydration subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 4 / 40 (10.00%) 4 | 2 / 40 (5.00%) 2 |
| Gout subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 40 (0.00%) 0 |
| Hypercalcaemia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 2 / 40 (5.00%) 2 | 2 / 40 (5.00%) 2 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 1 / 40 (2.50%) 1 | 4 / 40 (10.00%) 4 |
| Hyperuricaemia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 3 / 40 (7.50%) 4 | 1 / 40 (2.50%) 1 |
| Hypokalaemia subjects affected / exposed occurrences (all) | 0 / 9 (0.00%) 0 | 0 / 40 (0.00%) 0 | 5 / 40 (12.50%) 8 |
| Hypomagnesaemia subjects affected / exposed occurrences (all) | 1 / 9 (11.11%) 1 | 1 / 40 (2.50%) 1 | 2 / 40 (5.00%) 6 |
| Hyponatraemia | | | |

| | | | |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 2 / 40 (5.00%) | 1 / 40 (2.50%) |
| occurrences (all) | 0 | 2 | 1 |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 40 (0.00%) | 0 / 40 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 24 June 2013 | Additional cohorts of approximately 20 participants each (denoted Cohort C and Cohort D) to assess pinatuzumab vedotin and polatuzumab vedotin at a dose of 1.8 mg/kg in combination with RTX at a dose of 375 mg/m ² in participants with r/r FL were added; Participants enrolled into Cohorts C and D were not eligible to receive crossover treatment; Updated safety and efficacy information from the ongoing Phase I studies were provided; The definitions of PFS and OS were updated; Procedures for reporting non-serious adverse events of special interest and serious adverse events were updated. |
| 06 November 2014 | A Phase Ib/II portion of the study was added using obinutuzumab in combination with polatuzumab vedotin. Initially, a safety run-in of 6 participants with either r/r FL or DLBCL were treated with polatuzumab vedotin at 1.8 mg/kg in combination with obinutuzumab (denoted as Cohort E). The expansion cohorts were to contain 40 participants for each histology, FL or DLBCL (denoted Cohorts G and H); For obinutuzumab-containing cohorts (Cohorts E, G, and H), PET/CT scans were required for both FL and DLBCL. In the post-treatment follow-up period, participants were followed for response for up to 2 years after the last infusion of study treatment; The response criteria for NHL were updated. |
| 30 April 2015 | In addition to sites in the United States, sites worldwide started participating in the enrollment of participants into the non-randomized expansion cohorts (G and H) of the obinutuzumab portion of the study; The criteria for opening enrollment to the expansion portion of the study were modified; Guidelines for dose modification of polatuzumab vedotin were updated; Electronic patient-reported outcome (ePRO) assessments were removed for the obinutuzumab cohorts; Non-serious adverse events of special interest for this study were updated. |
| 03 October 2017 | Language was updated to include 18F-fluorodeoxyglucose-positron emission tomography (18F-FDG-PET; referred to as PET)/CT scans as a response assessment; Information regarding risks associated with ADCETRIS (brentuximab vedotin) was deleted; Language was updated to state second malignancies were to be recorded indefinitely (even if the study had been closed) for all participants enrolled in the obinutuzumab-containing cohorts and irrespective of new anti-lymphoma treatments. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported