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	

Results information

Result version number	v1
This version publication date	21 March 2018
First version publication date	21 March 2018

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	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.com
Scientific contact	Roche Trial Information Hotline, 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	Interim
Date of interim/final analysis	10 April 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 March 2017
Global end of trial reached?	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
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: 14
Country: Number of subjects enrolled	United States: 171
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	230
EEA total number of subjects	43

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	102
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, 230 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/m^2) 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/m^2 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/m^2 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	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/m^2 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/m^2 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/m^2 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	Cohort C (FL): RTX + Polatuzumab

Arm description:

Participants with r/r FL received RTX at a dose of 375 mg/m^2 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	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/m^2 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 1.8 mg/kg administered by IV infusion on Day 1 or 2 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	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 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	3	1	2
Not completed	60	58	18
Ongoing in Study	18	19	11
Consent withdrawn by subject	8	5	1
Progression of Disease	2	3	1
Adverse Event	-	1	-
Death	31	28	4
Unspecified	-	2	1
Lost to follow-up	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	39	40
Completed	0	0	0
Not completed	9	39	40
Ongoing in Study	5	31	14
Consent withdrawn by subject	1	2	3
Progression of Disease	-	1	2
Adverse Event	1	-	-
Death	2	5	20
Unspecified	-	-	1
Lost to follow-up	-	-	-

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/m^2) 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/m^2 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/m^2 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/m^2 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/m^2 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	39	40
Age Categorical Units: Subjects			
Age Continuous Units: years arithmetic mean standard deviation	 67.7 ± 9.7	 63.8 ± 11.6	 65.2 ± 15.3
Gender Categorical Units: Subjects			
Female	2	16	18
Male	7	23	22

Reporting group values	Total		
Number of subjects	230		
Age Categorical Units: Subjects			
Age Continuous Units: years arithmetic mean standard deviation	 -	 	
Gender Categorical Units: Subjects			
Female	95		
Male	135		

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/m^2) 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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.

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 (>/=) 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 >/=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: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.
[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+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 (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+Polatuzumab,Then RTX+Pinatuzumab			

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 >/=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 >/=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: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.
[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+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	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+Pinatuzumab			
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 [</=] mediastinum), or 3 (uptake less than [<] mediastinum but </=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: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.
[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 1.5 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+Pinatuzumab,Then RTX+Polatuzumab	Arm B (FL+DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab		
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 1.5 years)

End point values	Arm A (FL+DLBCL): RTX+Pinatuzumab,Then RTX+Polatuzumab	Arm B (FL+DLBCL): RTX+Polatuzumab,Then RTX+Pinatuzumab	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 1.5 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 3.5 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+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)	60.0	85.7	52.4	76.9

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)	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 3.5 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+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: 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 data cut-off date, up to approximately 4.5 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 data cut-off date, up to approximately 4.5 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+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: 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+Polatuzumab,Then RTX+Pinatuzumab			
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 </=mediastinum), or 3 (uptake <mediastinum but </=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

	Assessment as Determined by IRC per Lugano 2014 Response Criteria: Obinutuzumab-Containing Cohorts (Cohorts E, G, and H)[14]

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 </=mediastinum), or 3 (uptake <mediastinum but </=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 </=mediastinum), or 3 (uptake <mediastinum but </=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 (</=) 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		

27.0)	19.0)

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 LDi 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 LDi 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 >/=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 LDi 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 >/=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 </=mediastinum), or 3 (uptake <mediastinum but </=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 2.5 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+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	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+Polatuzumab,Then RTX+Pinatuzumab			
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 (Cmax) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

End point title	Maximum Observed Serum Concentration (Cmax) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)[18]

End point description:

Cmax 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+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	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+Polatuzumab,Then RTX+Pinatuzumab			
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+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	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+Polatuzumab,Then RTX+Pinatuzumab			
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 (t1/2) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

End point title	Half-Life (t1/2) of Rituximab: Rituximab Containing Regimens

	(Arms A and B, Cohort C)[20]

End point description:

t1/2 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+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	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+Polatuzumab,Then RTX+Pinatuzumab			
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 (Vss) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)

End point title	Volume of Distribution at Steady State (Vss) of Rituximab: Rituximab Containing Regimens (Arms A and B, Cohort C)[21]

End point description:

Vss 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+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	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+Polatuzumab,Then RTX+Pinatuzumab			
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+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	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+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	17		
Units: day*nanogram (ng)/mL				
arithmetic mean (standard deviation)	2840 (± 555)	3110 (± 828)		

Statistical analyses

No statistical analyses for this end point

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+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	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+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	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 (± 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 (± 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

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	20.0

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/m^2) 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/m^2 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/m^2 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/m^2 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/m^2 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%)	7 / 20 (35.00%)
number of deaths (all causes)	33	27	4
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
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
Seizure			

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
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
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
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%)	8 / 39 (20.51%)	17 / 40 (42.50%)
number of deaths (all causes)	2	5	21

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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (2.56%)	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 / 39 (2.56%)	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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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%)	1 / 39 (2.56%)	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
Subdural Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	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 / 39 (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 / 39 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial flutter			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (2.56%)	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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (2.56%)	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 / 39 (5.13%)	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 / 39 (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 / 39 (5.13%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (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 / 39 (2.56%)	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,Then RTX+Polatuzumab	Arm B (FL+DLBCL): RTX+Polatuzumab,Then 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	0 / 63 (0.00%)	0 / 59 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	11 / 63 (17.46%)	16 / 59 (27.12%)	0 / 20 (0.00%)
occurrences (all)	14	26	0
Chest pain			
subjects affected / exposed	4 / 63 (6.35%)	6 / 59 (10.17%)	2 / 20 (10.00%)
occurrences (all)	5	7	2
Chills			
subjects affected / exposed	5 / 63 (7.94%)	4 / 59 (6.78%)	3 / 20 (15.00%)
occurrences (all)	7	6	6
Fatigue			
subjects affected / exposed	32 / 63 (50.79%)	34 / 59 (57.63%)	13 / 20 (65.00%)
occurrences (all)	49	51	19
Feeling hot			
subjects affected / exposed	0 / 63 (0.00%)	0 / 59 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Gait disturbance			
subjects affected / exposed	1 / 63 (1.59%)	3 / 59 (5.08%)	1 / 20 (5.00%)
occurrences (all)	1	4	2
Influenza like illness			
subjects affected / exposed	0 / 63 (0.00%)	8 / 59 (13.56%)	0 / 20 (0.00%)
occurrences (all)	0	14	0
Malaise			
subjects affected / exposed	1 / 63 (1.59%)	2 / 59 (3.39%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
Nodule			
subjects affected / exposed	0 / 63 (0.00%)	0 / 59 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	6 / 63 (9.52%)	8 / 59 (13.56%)	3 / 20 (15.00%)
occurrences (all)	8	11	4
Pain			
subjects affected / exposed	5 / 63 (7.94%)	1 / 59 (1.69%)	3 / 20 (15.00%)
occurrences (all)	5	2	4
Peripheral swelling			
subjects affected / exposed	1 / 63 (1.59%)	2 / 59 (3.39%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Pyrexia			
subjects affected / exposed	15 / 63 (23.81%)	9 / 59 (15.25%)	5 / 20 (25.00%)
occurrences (all)	19	12	20
Unevaluable event			
subjects affected / exposed	0 / 63 (0.00%)	0 / 59 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 63 (0.00%)	0 / 59 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 63 (0.00%)	0 / 59 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	9 / 63 (14.29%)	15 / 59 (25.42%)	3 / 20 (15.00%)
occurrences (all)	10	16	6
Dysphonia			
subjects affected / exposed	1 / 63 (1.59%)	2 / 59 (3.39%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
Dyspnoea			
subjects affected / exposed	11 / 63 (17.46%)	11 / 59 (18.64%)	2 / 20 (10.00%)
occurrences (all)	13	14	4
Dyspnoea exertional			
subjects affected / exposed	1 / 63 (1.59%)	0 / 59 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
Epistaxis			
subjects affected / exposed	3 / 63 (4.76%)	1 / 59 (1.69%)	2 / 20 (10.00%)
occurrences (all)	3	1	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
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
Excoriation			
subjects affected / exposed	0 / 63 (0.00%)	0 / 59 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
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
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%)	6 / 59 (10.17%)	1 / 20 (5.00%)
occurrences (all)	2	6	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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 63 (14.29%)	10 / 59 (16.95%)	1 / 20 (5.00%)
occurrences (all)	9	12	1
Lymphadenopathy			
subjects affected / exposed	0 / 63 (0.00%)	1 / 59 (1.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Neutropenia			
subjects affected / exposed	19 / 63 (30.16%)	15 / 59 (25.42%)	8 / 20 (40.00%)
occurrences (all)	49	31	16
Thrombocytopenia			
subjects affected / exposed	3 / 63 (4.76%)	2 / 59 (3.39%)	0 / 20 (0.00%)
occurrences (all)	9	3	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 63 (0.00%)	1 / 59 (1.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Ear pain			
subjects affected / exposed	1 / 63 (1.59%)	0 / 59 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Vertigo			
subjects affected / exposed	2 / 63 (3.17%)	1 / 59 (1.69%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
Eye disorders			

Dry eye			
subjects affected / exposed	2 / 63 (3.17%)	0 / 59 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
Eye pain			
subjects affected / exposed	1 / 63 (1.59%)	0 / 59 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Lacrimation increased			
subjects affected / exposed	0 / 63 (0.00%)	0 / 59 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	6 / 63 (9.52%)	2 / 59 (3.39%)	2 / 20 (10.00%)
occurrences (all)	11	2	2
Visual impairment			
subjects affected / exposed	1 / 63 (1.59%)	1 / 59 (1.69%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	2 / 63 (3.17%)	3 / 59 (5.08%)	1 / 20 (5.00%)
occurrences (all)	2	3	1
Abdominal distension			
subjects affected / exposed	1 / 63 (1.59%)	2 / 59 (3.39%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Abdominal pain			
subjects affected / exposed	11 / 63 (17.46%)	11 / 59 (18.64%)	2 / 20 (10.00%)
occurrences (all)	15	15	2
Abdominal pain lower			
subjects affected / exposed	2 / 63 (3.17%)	1 / 59 (1.69%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
Abdominal pain upper			
subjects affected / exposed	1 / 63 (1.59%)	4 / 59 (6.78%)	2 / 20 (10.00%)
occurrences (all)	1	4	2
Constipation			
subjects affected / exposed	18 / 63 (28.57%)	14 / 59 (23.73%)	5 / 20 (25.00%)
occurrences (all)	21	18	6
Diarrhoea			

subjects affected / exposed	28 / 63 (44.44%)	25 / 59 (42.37%)	5 / 20 (25.00%)
occurrences (all)	42	43	7
Dry mouth			
subjects affected / exposed	5 / 63 (7.94%)	5 / 59 (8.47%)	1 / 20 (5.00%)
occurrences (all)	5	6	1
Dyspepsia			
subjects affected / exposed	4 / 63 (6.35%)	8 / 59 (13.56%)	3 / 20 (15.00%)
occurrences (all)	4	9	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
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	11	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	10	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%)	2 / 59 (3.39%)	1 / 20 (5.00%)
occurrences (all)	0	2	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	5 / 63 (7.94%)	2 / 59 (3.39%)	3 / 20 (15.00%)
occurrences (all)	5	2	3
Urinary tract infection			
subjects affected / exposed	6 / 63 (9.52%)	2 / 59 (3.39%)	0 / 20 (0.00%)
occurrences (all)	6	2	0
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 63 (4.76%)	1 / 59 (1.69%)	4 / 20 (20.00%)
occurrences (all)	3	3	4
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	13 / 63 (20.63%)	17 / 59 (28.81%)	4 / 20 (20.00%)
occurrences (all)	19	18	10
Dehydration			
subjects affected / exposed	6 / 63 (9.52%)	3 / 59 (5.08%)	2 / 20 (10.00%)
occurrences (all)	7	3	2
Gout			
subjects affected / exposed	0 / 63 (0.00%)	1 / 59 (1.69%)	1 / 20 (5.00%)
occurrences (all)	0	1	4
Hypercalcaemia			
subjects affected / exposed	1 / 63 (1.59%)	1 / 59 (1.69%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Hyperglycaemia			
subjects affected / exposed	8 / 63 (12.70%)	4 / 59 (6.78%)	2 / 20 (10.00%)
occurrences (all)	10	9	2
Hyperuricaemia			
subjects affected / exposed	2 / 63 (3.17%)	1 / 59 (1.69%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Hypokalaemia			
subjects affected / exposed	7 / 63 (11.11%)	8 / 59 (13.56%)	0 / 20 (0.00%)
occurrences (all)	11	13	0
Hypomagnesaemia			

subjects affected / exposed	6 / 63 (9.52%)	6 / 59 (10.17%)	1 / 20 (5.00%)
occurrences (all)	5	6	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 / 39 (94.87%)	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 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	1 / 40 (2.50%)
occurrences (all)	0	5	1
Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	4 / 40 (10.00%)
occurrences (all)	0	2	5

Orthostatic hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Thrombolysis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 39 (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 / 39 (7.69%)	8 / 40 (20.00%)
occurrences (all)	1	4	9
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 9 (0.00%)	8 / 39 (20.51%)	5 / 40 (12.50%)
occurrences (all)	0	9	6
Fatigue			
subjects affected / exposed	5 / 9 (55.56%)	20 / 39 (51.28%)	11 / 40 (27.50%)
occurrences (all)	6	26	12
Feeling hot			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	0	1	3
Influenza like illness			
subjects affected / exposed	1 / 9 (11.11%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Nodule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	3 / 40 (7.50%)
occurrences (all)	0	3	4
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	2 / 9 (22.22%)	5 / 39 (12.82%)	3 / 40 (7.50%)
occurrences (all)	2	5	3
Unevaluable event			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 9 (11.11%)	7 / 39 (17.95%)	7 / 40 (17.50%)
occurrences (all)	1	7	8
Dysphonia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	2 / 40 (5.00%)
occurrences (all)	0	3	2
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	5 / 39 (12.82%)	8 / 40 (20.00%)
occurrences (all)	0	5	9
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	2
Epistaxis			

subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	0	2	2
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	2 / 40 (5.00%)
occurrences (all)	0	2	2
Nasal congestion			
subjects affected / exposed	1 / 9 (11.11%)	5 / 39 (12.82%)	3 / 40 (7.50%)
occurrences (all)	1	5	3
Oropharyngeal pain			
subjects affected / exposed	1 / 9 (11.11%)	2 / 39 (5.13%)	3 / 40 (7.50%)
occurrences (all)	1	2	3
Orthopnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	2 / 9 (22.22%)	4 / 39 (10.26%)	2 / 40 (5.00%)
occurrences (all)	2	4	2
Pulmonary congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 9 (22.22%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	2	1	2
Sinus congestion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Sneezing			

subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Depression			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Hallucination olfactory			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 39 (2.56%)	6 / 40 (15.00%)
occurrences (all)	1	1	6
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	3 / 39 (7.69%)	1 / 40 (2.50%)
occurrences (all)	1	3	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	2 / 40 (5.00%)
occurrences (all)	0	5	2
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	1	1	3
Blood potassium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	3	1
Neutrophil count decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 39 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	3
Protein total decreased			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	1	4	1
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Excoriation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	2 / 40 (5.00%)
occurrences (all)	0	3	2
Infusion related reaction			
subjects affected / exposed	1 / 9 (11.11%)	7 / 39 (17.95%)	3 / 40 (7.50%)
occurrences (all)	1	8	3
Procedural pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 9 (11.11%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	1	1	2
Cardiac tamponade			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	4	0
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cluster headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Cubital tunnel syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	6 / 39 (15.38%)	4 / 40 (10.00%)
occurrences (all)	0	7	4
Dysgeusia			

subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	1 / 40 (2.50%)
occurrences (all)	0	4	1
Headache			
subjects affected / exposed	1 / 9 (11.11%)	10 / 39 (25.64%)	6 / 40 (15.00%)
occurrences (all)	1	10	6
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	2
Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nerve compression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 9 (11.11%)	8 / 39 (20.51%)	8 / 40 (20.00%)
occurrences (all)	1	13	9
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	3 / 40 (7.50%)
occurrences (all)	0	7	4
Peripheral motor neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	0 / 40 (0.00%)
occurrences (all)	0	4	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 9 (22.22%)	7 / 39 (17.95%)	2 / 40 (5.00%)
occurrences (all)	2	10	6
Restless legs syndrome			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	1 / 40 (2.50%)
occurrences (all)	0	5	1
Syncope			
subjects affected / exposed	1 / 9 (11.11%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	2 / 9 (22.22%)	4 / 39 (10.26%)	4 / 40 (10.00%)
occurrences (all)	2	4	4
Lymphadenopathy			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Neutropenia			
subjects affected / exposed	4 / 9 (44.44%)	8 / 39 (20.51%)	8 / 40 (20.00%)
occurrences (all)	7	12	16
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	4 / 40 (10.00%)
occurrences (all)	0	5	8
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	4	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	0 / 40 (0.00%)
occurrences (all)	0	3	0
Eye pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	3	1
Visual impairment			

subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	4 / 40 (10.00%)
occurrences (all)	0	4	5
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	3 / 40 (7.50%)
occurrences (all)	0	4	6
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	5 / 39 (12.82%)	4 / 40 (10.00%)
occurrences (all)	0	5	4
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	14 / 39 (35.90%)	8 / 40 (20.00%)
occurrences (all)	0	14	8
Diarrhoea			
subjects affected / exposed	3 / 9 (33.33%)	13 / 39 (33.33%)	14 / 40 (35.00%)
occurrences (all)	3	17	23
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	5 / 39 (12.82%)	3 / 40 (7.50%)
occurrences (all)	0	5	3
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Gastritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	11 / 39 (28.21%)	14 / 40 (35.00%)
occurrences (all)	0	14	15
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	8 / 39 (20.51%)	5 / 40 (12.50%)
occurrences (all)	0	8	5
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Brow ptosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			

subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	2 / 40 (5.00%)
occurrences (all)	0	3	2
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	1 / 40 (2.50%)
occurrences (all)	0	3	1
Hyperhidrosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Night sweats			
subjects affected / exposed	0 / 9 (0.00%)	6 / 39 (15.38%)	1 / 40 (2.50%)
occurrences (all)	0	7	1
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	7 / 39 (17.95%)	3 / 40 (7.50%)
occurrences (all)	0	9	3
Rash			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Rash erythematous			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Urinary hesitation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (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 / 39 (10.26%)	3 / 40 (7.50%)
occurrences (all)	2	5	3
Arthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	5 / 40 (12.50%)
occurrences (all)	0	2	6
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	0 / 40 (0.00%)
occurrences (all)	0	3	0
Muscle tightness			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Osteopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 9 (11.11%)	7 / 39 (17.95%)	5 / 40 (12.50%)
occurrences (all)	1	10	6
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
Ear infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	0	1	3
Infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Oral candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pilonidal cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 9 (22.22%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	5	3	0
Tooth infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	1 / 40 (2.50%)
occurrences (all)	0	3	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)	7 / 39 (17.95%)	5 / 40 (12.50%)
occurrences (all)	0	7	5
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	4 / 39 (10.26%)	2 / 40 (5.00%)
occurrences (all)	0	4	2
Gout			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	2 / 40 (5.00%)
occurrences (all)	0	2	2
Hyperglycaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 39 (2.56%)	4 / 40 (10.00%)
occurrences (all)	1	1	4
Hyperuricaemia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 39 (7.69%)	1 / 40 (2.50%)
occurrences (all)	0	4	1
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	5 / 40 (12.50%)
occurrences (all)	0	0	8
Hypomagnesaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	1	1	6
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 39 (5.13%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 39 (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