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

Summary

EudraCT number	2015-001998-40
Trial protocol	IT
Global end of trial date	04 August 2022

Results information

Result version number	v1
This version publication date	16 August 2023
First version publication date	16 August 2023

Trial information

Trial identification

Sponsor protocol code	GO29833

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02611323
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, + 41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, + 41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 August 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to evaluate the safety, efficacy, and pharmacokinetics of induction treatment with obinutuzumab, polatuzumab vedotin, and venetoclax in participants with relapsed or refractory FL, and with rituximab, polatuzumab vedotin, and venetoclax in participants with DLBCL.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 March 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 53
Country: Number of subjects enrolled	Italy: 29
Country: Number of subjects enrolled	United States: 49
Worldwide total number of subjects	131
EEA total number of subjects	29

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	68
From 65 to 84 years	60
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

Participants took part in this study at 23 investigative centers in Australia, Italy, & the United States from 09 March 2016 to 04 August 2022. Study consisted of two phases: dose-escalation phase & dose-expansion phase. All eligible participants in both the phases received induction treatment, & post-induction treatment as indicated.

Pre-assignment

Screening details:

Participants were enrolled in in the study to receive polatuzumab vedotin + venetoclax & fixed doses of rituximab/obinutuzumab. Of the 133 enrolled participants, 131 participants received at least one dose of the study drug & their intended treatment. 2 participants did not receive any study treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	FL Dose Escalation: 1.4P+400V+1000G

Arm description:

Participants received venetoclax, 400 milligrams (mg), orally, once daily (QD) on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, intravenous (IV) infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 milligrams per kilograms (mg/kg), IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved complete response (CR), partial response (PR), or stable disease (SD) at end of induction (EOI) received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Arm type	Experimental
Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by maintenance treatment (for participants with CR, PR or SD) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Investigational medicinal product name	Obinituzumab
Investigational medicinal product code	
Other name	RO5072759
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Arm title	FL Dose Escalation: 1.4P+200V+1000G

Arm description:

Participants received venetoclax, 200 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 200 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion, Infusion
Routes of administration	Intravenous use, Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Obinituzumab
Investigational medicinal product code	
Other name	RO5072759
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by maintenance treatment (for participants with CR, PR or SD) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Arm title	FL Dose Escalation: 1.8P+400V+1000G

Arm description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Arm type	Experimental

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Obinituzumab
Investigational medicinal product code	
Other name	RO5072759
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by maintenance treatment (for participants with CR, PR or SD) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Arm title	FL Dose Escalation: 1.4P+600V+1000G

Arm description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Arm type	Experimental
Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by maintenance treatment (for participants with CR, PR or SD) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Investigational medicinal product name	Obinituzumab
Investigational medicinal product code	
Other name	RO5072759
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Arm title	FL Dose Escalation: 1.8P+600V+1000G

Arm description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Obinituzumab
Investigational medicinal product code	
Other name	RO5072759
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by maintenance treatment (for participants with CR, PR or SD) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Arm title	FL Dose Escalation: 1.8P+800V+1000G

Arm description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Arm type	Experimental

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Obinituzumab
Investigational medicinal product code	
Other name	RO5072759
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by maintenance treatment (for participants with CR, PR or SD) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Arm title	FL: Dose Expansion: 1.8P+800V+1000G

Arm description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Obinituzumab
Investigational medicinal product code	
Other name	RO5072759
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by maintenance treatment (for participants with CR, PR or SD) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Arm title	DLBCL: Dose Escalation: 1.8P+400V+375R

Arm description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 milligrams per square metre (mg/m^2), IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 400 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	RO0452294
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received rituximab, 375 mg/m^2, IV, infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 8 months.

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by consolidation treatment (for participants with CR or PR) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Arm title	DLBCL Dose Escalation: 1.8P+600V+375R

Arm description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 600 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Arm type	Experimental

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by consolidation treatment (for participants with CR or PR) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	RO0452294
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received rituximab, 375 mg/m^2, IV, infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 8 months.

Arm title	DLBCL Dose Escalation: 1.8P+800V+375R

Arm description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Arm type	Experimental
Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by consolidation treatment (for participants with CR or PR) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	RO0452294
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received rituximab, 375 mg/m^2, IV, infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 8 months.

Arm title	DLBCL Dose Expansion: 1.8P+800V+375R

Arm description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Arm type	Experimental
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	RO0452294
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received rituximab, 375 mg/m^2, IV, infusion on Day 1 of Cycle 1 to 6 followed by consolidation treatment (for participants with CR or PR) at a dose of 375 mg/m^2 via IV infusion on Day 1 of every other month until disease progression or unacceptable toxicity for up to 8 months.

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	GDC-0199
Other name	ABT-199; RO5537382
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 followed by consolidation treatment (for participants with CR or PR) at a dose of 400 mg, orally, QD until disease progression or unacceptable toxicity for up to 8 months.

Investigational medicinal product name	Polatuzumab vedotin
Investigational medicinal product code	DCDS4501A
Other name	RO5541077
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

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

Number of subjects in period 1	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G
Started	7	3	3
Completed	2	2	3
Not completed	5	1	0
Adverse event, serious fatal	3	1	-
Consent withdrawn by subject	1	-	-
Progressive Disease	-	-	-
Lost to follow-up	1	-	-
Found Another Malignancy After Starting Trial	-	-	-

Number of subjects in period 1	FL Dose Escalation: 1.4P+600V+1000G	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G
Started	3	9	8
Completed	3	8	7
Not completed	0	1	1
Adverse event, serious fatal	-	1	1
Consent withdrawn by subject	-	-	-
Progressive Disease	-	-	-
Lost to follow-up	-	-	-
Found Another Malignancy After Starting Trial	-	-	-

Number of subjects in period 1	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+375R	DLBCL Dose Escalation: 1.8P+600V+375R
Started	41	3	6
Completed	30	2	2
Not completed	11	1	4
Adverse event, serious fatal	8	-	4
Consent withdrawn by subject	-	1	-
Progressive Disease	-	-	-
Lost to follow-up	3	-	-
Found Another Malignancy After Starting Trial	-	-	-

Number of subjects in period 1	DLBCL Dose Escalation: 1.8P+800V+375R	DLBCL Dose Expansion: 1.8P+800V+375R
Started	8	40
Completed	0	11
Not completed	8	29
Adverse event, serious fatal	6	26
Consent withdrawn by subject	1	-
Progressive Disease	-	1
Lost to follow-up	-	2
Found Another Malignancy After Starting Trial	1	-

Reporting groups

Reporting group title	FL Dose Escalation: 1.4P+400V+1000G

Reporting group description:

Participants received venetoclax, 400 milligrams (mg), orally, once daily (QD) on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, intravenous (IV) infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 milligrams per kilograms (mg/kg), IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved complete response (CR), partial response (PR), or stable disease (SD) at end of induction (EOI) received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.4P+200V+1000G

Reporting group description:

Participants received venetoclax, 200 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 200 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+400V+1000G

Reporting group description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.4P+600V+1000G

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+600V+1000G

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+800V+1000G

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL: Dose Expansion: 1.8P+800V+1000G

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	DLBCL: Dose Escalation: 1.8P+400V+375R

Reporting group description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 milligrams per square metre (mg/m^2), IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 400 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Escalation: 1.8P+600V+375R

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 600 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Escalation: 1.8P+800V+375R

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Expansion: 1.8P+800V+375R

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G
Number of subjects	7	3	3
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	58.9	61.3	56.7
standard deviation	± 6.8	± 8.5	± 13.6
Sex: Female, Male Units: participants			
Female	3	1	0
Male	4	2	3

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	7	3	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	3	3
Not Stated	0	0	0
Unknown	0	0	0

Reporting group values	FL Dose Escalation: 1.4P+600V+1000G	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G
Number of subjects	3	9	8
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	58.3	64.6	58.0
standard deviation	± 10.3	± 6.1	± 11.9
Sex: Female, Male Units: participants			
Female	0	4	4
Male	3	5	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	8	7
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	8	8
Not Stated	0	1	0
Unknown	0	0	0

Reporting group values	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+375R	DLBCL Dose Escalation: 1.8P+600V+375R
Number of subjects	41	3	6

Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	62.2	56.0	58.7
standard deviation	± 11.3	± 16.5	± 17.4
Sex: Female, Male Units: participants			
Female	20	2	4
Male	21	1	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	34	2	6
More than one race	0	0	0
Unknown or Not Reported	6	0	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	3	0	0
Not Hispanic or Latino	30	3	6
Not Stated	6	0	0
Unknown	2	0	0

Reporting group values	DLBCL Dose Escalation: 1.8P+800V+375R	DLBCL Dose Expansion: 1.8P+800V+375R	Total
Number of subjects	8	40	131
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	67.4	65.8	
standard deviation	± 15.2	± 9.6	-
Sex: Female, Male Units: participants			
Female	5	18	61
Male	3	22	70
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	2	4
White	6	30	109
More than one race	0	1	1
Unknown or Not Reported	1	6	15

Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	3
Not Hispanic or Latino	7	31	109
Not Stated	1	6	14
Unknown	0	3	5

End points reporting groups

Reporting group title	FL Dose Escalation: 1.4P+400V+1000G

Reporting group description:

Participants received venetoclax, 400 milligrams (mg), orally, once daily (QD) on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, intravenous (IV) infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 milligrams per kilograms (mg/kg), IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved complete response (CR), partial response (PR), or stable disease (SD) at end of induction (EOI) received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.4P+200V+1000G

Reporting group description:

Participants received venetoclax, 200 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 200 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+400V+1000G

Reporting group description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.4P+600V+1000G

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+600V+1000G

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+800V+1000G

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL: Dose Expansion: 1.8P+800V+1000G

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	DLBCL: Dose Escalation: 1.8P+400V+375R

Reporting group description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 milligrams per square metre (mg/m^2), IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 400 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Escalation: 1.8P+600V+375R

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 600 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Escalation: 1.8P+800V+375R

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Expansion: 1.8P+800V+375R

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

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

End point title	Percentage of Participants with CR at EOI Determined by an Independent Review Committee (IRC) on the Basis of Positron Emission Tomography (PET) and Computed Tomography (CT) Scans[1][2]

End point description:

CR at EOI was assessed by IRC according to modified Lugano Response Criteria (MLRC) for Malignant Lymphoma 2014 using PET-CT scan. CR =complete metabolic response (MR) in lymph nodes & extra lymphatic sites (ELS) with a score of 1, 2, or 3, with/without a residual mass on PET 5-point scale (5-PS), where 1=no uptake above background; 2= uptake ≤mediastinum; 3= uptake >mediastinum but ≤liver; 4=uptake moderately > liver; 5=uptake markedly higher than liver &/or new lesions. No new lesions; no evidence of fluorodeoxyglucose (FDG)-avid disease in bone marrow. Efficacy evaluable population=participants in the dose expansion arms who received at least one dose of any component of the combination. As pre-specified in the protocol, participants who received polatuzumab vedotin &

venetoclax at recommended phase 2 dose (RP2D) in dose-escalation phase were also analysed in addition to expansion phase participants for efficacy analysis. Percentages have been rounded off to first decimal point.

End point type	Primary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21 days)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No descriptive statistics were planned for this endpoint. Point estimates are presented, along with corresponding two-sided 90% Clopper-Pearson exact CIs.
[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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	100 (68.77 to 100.00)	51.2 (37.44 to 64.86)	25 (4.64 to 59.97)	32.5 (20.41 to 46.63)

Statistical analyses

No statistical analyses for this end point

Primary: FL Cohorts: Percentage of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	FL Cohorts: Percentage of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs)[3][4]

End point description:

An AE = as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE could therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Any new disease or worsening of an existing disease were also considered as AEs. An SAE = any AE that was fatal, life threatening, required prolonged inpatient hospitalization, resulted in significant disability or resulted in a congenital anomaly to a mother exposed to study treatment. AEs and SAEs were reported based on the National Cancer Institute Common Terminology Criteria for AEs, version 4.0 (NCI-CTCAE, v4.0). Percentages have been rounded off to the first decimal point. Safety-evaluable population included all participants who received at least one dose of any component of the combination.

End point type	Primary

End point timeframe:

From study start to 24 months after last dose of study drug (approximately 42 months)

Notes:

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

[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: Endpoint is reporting data only for FL cohorts. Hence, DLBCL cohorts have not been included.

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: percentage of participants				
number (not applicable)				
AEs	100	100	100	100
SAEs	57.1	33.3	33.3	0

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	8	41	
Units: percentage of participants				
number (not applicable)				
AEs	100	100	100	
SAEs	22.2	75.0	34.1	

Statistical analyses

No statistical analyses for this end point

Primary: DLBCL Cohorts: Percentage of Participants with AEs and SAEs

End point title	DLBCL Cohorts: Percentage of Participants with AEs and

End point description:

An AE was defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE could therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Any new disease or worsening of an existing disease were also considered as AEs. An SAE was defined as any AE that was fatal, life threatening, requires prolonged inpatient hospitalization, resulted in significant disability or resulted in a congenital anomaly to a mother exposed to study treatment. AEs and SAEs were reported based on the NCI-CTCAE, v4.0. Percentages have been rounded off to the first decimal point. Safety-evaluable population included all participants who received at least one dose of any component of the combination.

End point type	Primary

End point timeframe:

From study start to 3 months after last dose of study drug (approximately 21 months)

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: No descriptive statistics were planned for this endpoint.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting data only for the DLBCL arms and hence FL arms have not been included here.

End point values	DLBCL: Dose Escalation: 1.8P+400V+37	DLBCL Dose Escalation: 1.8P+600V+37	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	8	40
Units: percentage of participants				
number (not applicable)				
AEs	100	100	87.5	97.5
SAEs	100	66.7	25.0	30.0

Statistical analyses

No statistical analyses for this end point

Primary: RP2D of Polatuzumab Vedotin

End point title	RP2D of Polatuzumab Vedotin[7][8]

End point description:

RP2D was defined as the highest dose with acceptable toxicity as determined from dose-escalation phase. The RP2D of polatuzumab vedotin when given in combination with fixed dose of obinutuzumab in participants with FL was determined. Safety-evaluable population included all participants who received at least one dose of any component of the combination.

End point type	Primary

End point timeframe:

Day 1 of Cycle 1 to Day 1 of Cycle 2 (1 cycle=21 days) in dose-escalation phase

Notes:

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

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is reporting data for all arms that received polatuzumab at RP2D in the dose escalation phase. Hence, other dose escalation and expansion arms have not been included.

End point values	FL Dose Escalation: 1.8P+800V+1000G			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: mg/kg				
number (not applicable)	1.8			

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Participants with Dose-Limiting Toxicities (DLTs

End point description:

DLT=any one of the events that occurred in first treatment cycle & per the investigator was related to

study treatment. Any AE that lead to a delay of > 14 days in start of next treatment cycle; Any Grade 3/4 non-hematologic AE with few exceptions; Any increase in hepatic transaminase >3×baseline(BL) & increase in direct bilirubin >2×upper limit of normal (ULN), without any findings of cholestasis/jaundice/signs of hepatic dysfunction & in absence of other contributory factors; Grade1 alanine transaminase (ALT)/aspartate transaminase (AST) elevation at BL as result of liver metastases, only a Grade ≥3 elevation, also ≥3×BL lasting >7 days; Hematologic AE meeting protocol specified criteria. Events were graded per National Cancer Institute Common Terminology Criteria for AEs, version 4.0 NCI CTCAE v4.0. Safety-evaluable population=all participants who received at least one dose of any component of the combination.

End point type	Primary

End point timeframe:

Day 1 of Cycle 1 to Day 1 of Cycle 2 (1 cycle=21 days) in dose-escalation phase

Notes:

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

[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: DLTs were analyzed in the dose escalation phase alone and hence only dose escalation arms have been included for this endpoint.

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: participants	1	0	0	0

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+37	DLBCL Dose Escalation: 1.8P+600V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	3	6
Units: participants	2	1	0	1

End point values	DLBCL Dose Escalation: 1.8P+800V+37			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: RP2D of Venetoclax

End point title	RP2D of Venetoclax[11][12]

End point description:

RP2D was defined as the highest dose with acceptable toxicity as determined from dose-escalation phase. The RP2D of venetoclax when given in combination with fixed dose of polatuzumab vedotin in participants with FL and DLBCL was determined. Safety-evaluable population included all participants who received at least one dose of any component of the combination.

End point type	Primary

End point timeframe:

Day 1 of Cycle 1 to Day 1 of Cycle 2 (1 cycle=21 days) in dose-escalation phase

Notes:

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

[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: This endpoint is reporting data for all arms that received venetoclax at RP2D in the dose escalation phase. Hence, other dose escalation and expansion arms have not been included.

End point values	FL Dose Escalation: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	8		
Units: mg	800	800		

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with CR at EOI, Determined by the Investigator on the Basis of PET-CT scans[13]

End point description:

CR at EOI was assessed by Investigator according to MLRC. Per MLRC, CR based on PET-CT was defined as complete MR in lymph nodes and ELS with a score of 1, 2, or 3 with or without residual mass, on 5PS where 1=no uptake above background; 2=uptake ≤ mediastinum; 3=uptake > mediastinum but ≤ liver; 4=uptake moderately > liver; 5=uptake markedly higher than liver and/or new lesions; no evidence of FDG-avid disease in bone marrow. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Efficacy evaluable population included participants in the dose expansion arms who received at least one dose of any component of the combination. As pre-specified in the protocol, participants who received polatuzumab vedotin and venetoclax at RP2D in dose-escalation phase were also analysed in addition to expansion phase participants for efficacy analysis. Percentages have been rounded off to first decimal point.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21days)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	100 (68.77 to 100.00)	51.2 (37.44 to 64.86)	25.0 (4.64 to 59.97)	32.5 (20.41 to 46.63)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with CR at EOI, Determined by the IRC on the Basis of CT Scans Alone[14]

End point description:

CR at EOI was determined by IRC according to the MLRC. Per MLRC, CR based on CT = complete radiologic response in lymph nodes & ELS with target nodes/nodal masses regressing to ≤ 1.5 centimeter (cm) in longest transverse diameter (LDi) & no ELS of disease; organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, immunohistochemistry (IHC) negative. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Efficacy evaluable population included participants in the dose expansion arms who received at least one dose of any component of the combination. As pre-specified in the protocol, participants who received polatuzumab vedotin and venetoclax at RP2D in dose-escalation phase were also analysed in addition to expansion phase participants for efficacy analysis. Overall number analysed is the number of participants with data available for analysis. Percentages have been rounded off to the first decimal point.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21days)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	6	34
Units: percentage of participants				
number (confidence interval 90%)	62.5 (28.92 to 88.89)	36.6 (24.08 to 50.61)	16.7 (0.85 to 58.18)	26.5 (14.56 to 41.65)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with CR at EOI, Determined by the Investigator on the Basis of CT Scans Alone[15]

End point description:

CR at EOI was determined by Investigator according to the MLRC. Per MLRC, CR based on CT was defined as complete radiologic response in lymph nodes and ELS with target nodes/nodal masses regressing to ≤ 1.5 cm in LDi and no ELS of disease; organ enlargement regressing to normal; no new lesions; normal bone marrow by morphology, if indeterminate, IHC negative. 90% CI for percentage of responders was calculated using Clopper-Pearson method. Efficacy evaluable population included participants in the dose expansion arms who received at least one dose of any component of the combination. As pre-specified in the protocol, participants who received polatuzumab vedotin and venetoclax at RP2D in dose-escalation phase were also analysed in addition to expansion phase participants for efficacy analysis. Percentages have been rounded off to the first decimal point.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21days)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	75.0 (40.03 to 95.36)	29.3 (17.84 to 43.07)	25.0 (4.64 to 59.97)	22.5 (12.27 to 35.98)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with Objective Response (OR) at EOI, Determined by an IRC on the Basis of PET and CT Scans[16]

End point description:

OR=% of participants with CR/PR as assessed=IRC per MLRC. Per MLRC CR per PET-CT=complete MR in lymph nodes &ELS with score of 1/2/3 with/without residual mass on 5PS, where 1=no uptake above background; 2=uptake ≤mediastinum; 3=uptake>mediastinum but ≤liver; 4=uptake moderately >liver5=uptake markedly >than liver &/or new lesions;no evidence of FDG-avid disease in bone marrow. PR per PET-CT=partial MR in lymph nodes &ELS with score of 4/5 with < uptake compared with BL & residual masses of any size: at interim/end of treatment, residual uptake >than uptake in normal bone marrow but <compared to BL. Efficacy evaluable population=participants in dose expansion arms who received at least one dose of any component of the combination. As pre-specified in protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation were also analysed in addition to expansion phase participants for efficacy analysis. Percentages are rounded off to first decimal point

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21days)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	100.0 (68.77 to 100.00)	70.7 (56.93 to 82.16)	25.0 (4.64 to 59.97)	37.5 (24.73 to 51.72)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with OR at EOI, Determined by the Investigator on the Basis of PET and CT Scans[17]

End point description:

OR=participants with CR/PR as assessed=IRC per MLRC. Per MLRC CR based on PET-CT=complete MR in lymph nodes &ELS with score of 1/2/3 with/without residual mass on 5PS,where 1=no uptake above background;2=uptake ≤mediastinum;3=uptake>mediastinum but ≤liver; 4=uptake moderately >liver5=uptake markedly >than liver &/or new lesions;no evidence of FDG-avid disease in bone marrow. PR per PET-CT=partial MR in lymph nodes &ELS with score of 4/5 with < uptake compared with BL &residual masses of any size: at interim/end of treatment, residual uptake >than uptake in normal bone marrow but <compared to BL. Efficacy evaluable population=participants in dose expansion arms who received at least one dose of any component of the combination. As pre-specified in protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation were also analysed in addition to expansion phase participants for efficacy analysis. Percentages are rounded off to first decimal point.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21days)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	100.0 (68.77 to 100.00)	75.6 (62.15 to 86.13)	37.5 (11.11 to 71.08)	42.5 (29.18 to 56.69)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with OR at EOI, Determined by an IRC on the Basis of CT Scans Alone[18]

End point description:

OR=% of participants with CR/PR, per IRC per MLRC. Per MLRC, CR per CT=complete radiologic response in lymph nodes & ELS with target nodes/nodal masses regressing to ≤1.5 cm in LDi &no ELS of disease; organ enlargement regressing to normal; no new lesions; bone marrow normal by morphology, if indeterminate, IHC negative. PR per CT=partial remission in lymph nodes & ELS with ≥50% decrease in sum of products of greatest diameters (SPD) of up to 6 target measurable lymph nodes & extranodal sites, absent/normal/regressed but with no increase in non-measured lesions, spleen regressing by ≥50% in length beyond normal, no new sites of lesions. Efficacy evaluable population included participants in dose expansion arms who received at least one dose of any component of the combination. As pre-specified in protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase were also analysed in addition to expansion phase participants for efficacy analysis.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21days)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	87.5 (52.93 to 99.36)	82.9 (70.31 to 91.70)	25.0 (4.64 to 59.97)	37.5 (24.73 to 51.72)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with OR at EOI, Determined by the Investigator on the Basis of CT Scans Alone[19]

End point description:

OR=% of participants with CR/PR, per IRC per MLRC. Per MLRC, CR per CT=complete radiologic response in lymph nodes & ELS with target nodes/nodal masses regressing to ≤1.5 cm in LDi &no ELS of disease; organ enlargement regressing to normal; no new lesions; bone marrow normal by morphology, if indeterminate, IHC negative. PR per CT=partial remission in lymph nodes & ELS with ≥50% decrease in SPD of up to 6 target measurable lymph nodes &extranodal sites, absent/normal/regressed but with no increase in non-measured lesions, spleen regressing by ≥50% in length beyond normal, no new sites of lesions. Efficacy evaluable population=participants in dose expansion arms who received at least one dose of any component of the combination. As pre-specified in protocol, participants who received polatuzumab vedotin &venetoclax at RP2D in dose-escalation phase were also analysed in addition to expansion phase participants for efficacy analysis. Percentages are rounded off to first decimal point.

End point type	Secondary

End point timeframe:

6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 23 weeks) (1 cycle=21days)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	87.5 (52.93 to 99.36)	85.4 (73.15 to 93.43)	37.5 (11.11 to 71.08)	45.0 (31.46 to 59.12)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with Best Overall Response (BOR) of CR or PR, Determined by the Investigator on the Basis of CT Scans Alone[20]

End point description:

BOR=CR/PR per investigator based on CT per MLRC. Per MLRC, CR per CT=a complete radiologic response in lymph nodes &ELS with target nodes/nodal masses regressing to ≤1.5 cm in LDi &no ELS of disease; organ enlargement regressing to normal; no new lesions; bone marrow normal by morphology, if indeterminate, IHC negative. PR per CT=partial remission in lymph nodes & ELS with ≥50% decrease in SPD of up to 6 target measurable lymph nodes &extranodal sites, absent/normal/regressed but with no increase in non-measured lesions, spleen regressing by ≥50% in length beyond normal, no new sites of lesions. Efficacy evaluable population=participants in dose expansion arms who received at least one dose of any component of the combination. As pre-specified in protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation were also analysed in addition to

expansion phase participants for efficacy analysis. Percentages have been rounded off to first decimal point.

End point type	Secondary

End point timeframe:

Up to every 6 months until disease progression, the start of new anti-lymphoma treatment, or the end of the study, whichever occurs first (approximately 77 months)

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: As pre-specified in the protocol, participants who received polatuzumab vedotin & venetoclax at RP2D in dose-escalation phase and the dose expansion were only analyzed for efficacy analysis.

End point values	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	41	8	40
Units: percentage of participants				
number (confidence interval 90%)	100.0 (68.77 to 100.00)	87.8 (76.05 to 95.07)	50.0 (19.29 to 80.71)	72.5 (58.61 to 83.75)

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Obinutuzumab Concentration

End point title	Observed Serum Obinutuzumab Concentration[21]

End point description:

1 cycle = 21 days. Pharmacokinetics (PK) evaluable population included all participants who had at least one evaluable PK sample post dose for at least one analyte. Overall number analysed is the number of participants with data available for analysis. Number analysed is the number of participants with data available for analysis at the specified timepoint.Here, 9999= The data was not evaluable as the samples were below lower limit of quantification (BLLQ); 9999999= participants were not analysed for this PK endpoint at the given timepoint; 999999= Since only 1 participant was analysed, the geometric coefficient of variation was not evaluable.

End point type	Secondary

End point timeframe:

Pre-dose & 0.5 hours post-dose on Day 1 Cycles 1, 2, 4, & 6; and pre-dose on Day 1 of Months 2, 8, 14, 20; study drug discontinuation, Day 120 &1 year post-last dose (up to approximately 40 months)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is reporting data for all arms that received obinutuzumab. Hence, data is reported for FL cohorts only.

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: micrograms per milliliter (µg/mL)				

geometric mean (geometric coefficient of variation)				
Cycle (C)1 Day (D)1: Pre-dose (n=6,3,3,3,9,8,29)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D1 0.5 h: Post Dose (n=5,3,3,3,9,5,38)	310 (± 21.2)	360 (± 18.8)	169 (± 60.2)	342 (± 11.0)
C2 D1: Pre-dose (n=7,3,3,3,8,8,39)	327 (± 46.7)	498 (± 20.6)	288 (± 43.2)	395 (± 17.0)
C2 D1: 0.5 hours (h) Post Dose (n=7,3,3,3,8,8,39)	637 (± 32.0)	822 (± 17.0)	512 (± 56.1)	685 (± 17.8)
C4 D1: Pre-dose (n=7,3,2,3,8,7,36)	284 (± 50.9)	496 (± 25.3)	376 (± 9.6)	337 (± 12.0)
C4 D1: 0.5 h Post Dose (n=7,3,2,3,8,7,36)	534 (± 62.9)	842 (± 25.1)	709 (± 20.1)	732 (± 13.4)
C6 D1: Pre-dose (n=7,3,2,3,8,7,36)	288 (± 62.9)	582 (± 26.5)	338 (± 4.0)	335 (± 10.2)
C6 D1: 0.5 h Post Dose (n=6,3,2,3,8,7,36)	582 (± 26.8)	887 (± 19.6)	490 (± 65.2)	659 (± 14.3)
Maintenance Month 2 (6,3,1,3,8,7,31)	117 (± 471.2)	294 (± 53.3)	205 (± 999999)	192 (± 11.7)
Maintenance Month 8 (3,1,1,2,7,6,20)	148 (± 161.8)	184 (± 999999)	191 (± 999999)	114 (± 30.0)
Maintenance Month 14 (n=2,2,1,1,4,2,14)	189 (± 112.9)	226 (± 28.9)	197 (± 999999)	138 (± 999999)
Maintenance Month 20 (n=1,2,1,0,4,4,12)	242 (± 999999)	218 (± 30.7)	74.0 (± 999999)	9999999 (± 9999999)
Study Drug Discon. Visit (n=2,2,2,3,2,4,16)	9.61 (± 438943.9)	134 (± 1414.6)	4.48 (± 2973890.2)	66.6 (± 271.0)
Unscheduled Visit (n=3,0,0,0,1,1,6)	74.4 (± 28339.6)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)
Day 120 Post Last Dose (n=1,0,3,1,4,5,10)	39.9 (± 999999)	9999999 (± 9999999)	1.72 (± 1634893.3)	0.660 (± 999999)
One Year Post Last Dose (n=4,0,2,1,3,1,6)	0.0410 (± 20351.2)	9999999 (± 9999999)	0.0585 (± 372.7)	0.00680 (± 999999)

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	8	39	
Units: micrograms per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle (C)1 Day (D)1: Pre-dose (n=6,3,3,3,9,8,29)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	
C1 D1 0.5 h: Post Dose (n=5,3,3,3,9,5,38)	262 (± 106.0)	438 (± 17.8)	261 (± 115.1)	
C2 D1: Pre-dose (n=7,3,3,3,8,8,39)	435 (± 25.4)	497 (± 20.3)	422 (± 29.0)	
C2 D1: 0.5 hours (h) Post Dose (n=7,3,3,3,8,8,39)	800 (± 19.1)	975 (± 19.3)	834 (± 30.3)	
C4 D1: Pre-dose (n=7,3,2,3,8,7,36)	422 (± 20.3)	454 (± 37.2)	397 (± 40.5)	
C4 D1: 0.5 h Post Dose (n=7,3,2,3,8,7,36)	819 (± 18.6)	925 (± 26.9)	770 (± 25.6)	
C6 D1: Pre-dose (n=7,3,2,3,8,7,36)	437 (± 24.5)	420 (± 44.5)	428 (± 51.9)	
C6 D1: 0.5 h Post Dose (n=6,3,2,3,8,7,36)	857 (± 21.2)	841 (± 28.1)	807 (± 27.0)	
Maintenance Month 2 (6,3,1,3,8,7,31)	273 (± 63.4)	327 (± 57.6)	291 (± 60.8)	
Maintenance Month 8 (3,1,1,2,7,6,20)	170 (± 40.2)	210 (± 27.0)	168 (± 72.0)	

Maintenance Month 14 (n=2,2,1,1,4,2,14)	133 (± 23.5)	190 (± 17.9)	168 (± 41.3)	
Maintenance Month 20 (n=1,2,1,0,4,4,12)	156 (± 44.2)	144 (± 26.9)	180 (± 62.0)	
Study Drug Discon. Visit (n=2,2,2,3,2,4,16)	262 (± 11.9)	212 (± 34.8)	148 (± 110.1)	
Unscheduled Visit (n=3,0,0,0,1,1,6)	192 (± 999999)	144 (± 999999)	276 (± 124.8)	
Day 120 Post Last Dose (n=1,0,3,1,4,5,10)	41.2 (± 89.5)	94.6 (± 85.6)	44.1 (± 274.2)	
One Year Post Last Dose (n=4,0,2,1,3,1,6)	0.244 (± 716.1)	0.0820 (± 999999)	4.89 (± 9002.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Rituximab Concentration

End point title	Observed Serum Rituximab Concentration[22]

End point description:

PK evaluable population included all participants who had at least one evaluable PK sample post dose for at least one analyte. Overall number analysed is the number of participants with data available for analysis. Number analysed is the number of participants with data available for analysis at the specified timepoint.Here, 9999= The data was not evaluable as the samples were BLLQ; 999999= Since only 1 participant was analysed, the geometric coefficient of variation was not evaluable.

End point type	Secondary

End point timeframe:

Pre-dose and 0.5 hours post-dose on Day 1 of Cycles 1 and 6; pre-dose on Day 1 of Cycles 2 and 4; (1 cycle = 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: This endpoint is reporting data for all arms that received rituximab. Hence, data is reported for DLBCL cohorts only.

End point values	DLBCL: Dose Escalation: 1.8P+400V+37	DLBCL Dose Escalation: 1.8P+600V+37	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	6	6	39
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Pre-dose (n=2,2,1,9)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D1: 05 hPost Dose (n=2,6,6,39)	199 (± 25.4)	189 (± 6.8)	255 (± 14.0)	146 (± 159.3)
C2 D1: Within 5 h Pre-dose (n=2,6,6,36)	49.3 (± 17.2)	38.9 (± 61.7)	71.0 (± 42.1)	50.1 (± 30.5)
C4 D1: Within 5 h Pre-dose (n=2,2,4,29)	88.9 (± 11.1)	39.3 (± 71.0)	126 (± 16.5)	88.1 (± 43.4)
C6 D1: Pre-dose (n=2,1,3,24)	120 (± 8.8)	20.9 (± 999999)	151 (± 32.4)	117 (± 43.4)
C6 D1: 0.5 h Post Dose (n=2,1,3,23)	303 (± 12.4)	182 (± 999999)	229 (± 36.9)	308 (± 27.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Serum Concentration of Total Antibody to Polatuzumab Vedotin

End point title	Observed Serum Concentration of Total Antibody to Polatuzumab Vedotin

End point description:

Total antibody is an analyte of polatuzumab vedotin. PK evaluable population included all participants who had at least one evaluable PK sample post dose for at least one analyte. Overall number analysed is the number of participants with data available for analysis. Number analysed is the number of participants with data available for analysis at the specified timepoint. Here, 9999= The data was not evaluable as the samples were BLLQ; 99999= Geometric coefficient of variation was not evaluable as the samples were BLLQ; 999999= Since only 1 participant was analysed, the geometric coefficient of variation was not evaluable; 9999999= participants were not analysed for this PK endpoint at the given timepoint.

End point type	Secondary

End point timeframe:

Pre-dose on Day 1 of Cycles 1, 2 and 4; study drug discontinuation visit; Day 120 and 1 year post-last dose (up to approximately 16 months) (1 cycle=21 days)

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=7,3,3,3,8,7,41,2,6,7,39)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2 D1: Predose(n=7,3,3,3,8,8,40,3,6,6,37)	0.798 (± 404.2)	3.14 (± 29.4)	0.677 (± 6220.9)	2.03 (± 46.4)
C4 D1: Predose(n=7,3,2,3,8,7,36,3,2,4,30)	2.73 (± 76.1)	6.12 (± 26.1)	7.88 (± 9.5)	5.40 (± 18.4)
Study Drug Discn.Visit(n=2,2,2,3,4,4,17,1,1,4,14)	0.0250 (± 99999)	0.0250 (± 99999)	0.0534 (± 99999)	0.0250 (± 99999)
Unscheduled Visit (n=0,0,0,0,0,0,5,0,0,0,0)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)
Day 120 Post Last Dose (n=1,1,3,1,6,6,20,2,0,1,7)	0.0250 (± 999999)	0.0250 (± 999999)	0.0906 (± 99999)	0.0250 (± 999999)
One Year Post Last Dose (n=4,0,2,1,3,1,11,1,1,0,3)	0.0250 (± 99999)	9999999 (± 9999999)	0.0250 (± 99999)	0.0250 (± 999999)

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	41	3
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=7,3,3,3,8,7,41,2,6,7,39)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2 D1: Predose(n=7,3,3,3,8,8,40,3,6,6,37)	1.75 (± 63.2)	4.22 (± 31.1)	1.73 (± 265.3)	3.34 (± 56.6)
C4 D1: Predose(n=7,3,2,3,8,7,36,3,2,4,30)	5.72 (± 33.5)	8.19 (± 32.3)	5.88 (± 63.7)	6.84 (± 29.5)
Study Drug Discn.Visit(n=2,2,2,3,4,4,17,1,1,4,14)	0.0250 (± 99999)	0.0900 (± 99999)	0.110 (± 99999)	2.43 (± 999999)
Unscheduled Visit (n=0,0,0,0,0,0,5,0,0,0,0)	9999999 (± 9999999)	9999999 (± 9999999)	0.0571 (± 99999)	9999999 (± 9999999)
Day 120 Post Last Dose (n=1,1,3,1,6,6,20,2,0,1,7)	0.0832 (± 99999)	0.156 (± 99999)	0.494 (± 468.8)	0.385 (± 28.6)
One Year Post Last Dose (n=4,0,2,1,3,1,11,1,1,0,3)	0.0250 (± 99999)	0.0250 (± 999999)	0.0294 (± 99999)	0.0250 (± 999999)

End point values	DLBCL Dose Escalation: 1.8P+600V+37	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	39	
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=7,3,3,3,8,7,41,2,6,7,39)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	
C2 D1: Predose(n=7,3,3,3,8,8,40,3,6,6,37)	2.23 (± 83.5)	3.41 (± 30.9)	3.04 (± 70.8)	
C4 D1: Predose(n=7,3,2,3,8,7,36,3,2,4,30)	2.34 (± 82.1)	8.22 (± 17.0)	5.82 (± 45.7)	
Study Drug Discn.Visit(n=2,2,2,3,4,4,17,1,1,4,14)	4.71 (± 999999)	1.38 (± 203.0)	1.03 (± 471.1)	
Unscheduled Visit (n=0,0,0,0,0,0,5,0,0,0,0)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	
Day 120 Post Last Dose (n=1,1,3,1,6,6,20,2,0,1,7)	9999999 (± 9999999)	0.759 (± 999999)	1.37 (± 93.2)	
One Year Post Last Dose (n=4,0,2,1,3,1,11,1,1,0,3)	0.0250 (± 999999)	9999999 (± 9999999)	0.0457 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Concentration of Polatuzumab Vedotin Antibody-Conjugated Mono-Methyl Auristatin E (MMAE) (acMMAE)

End point title	Observed Plasma Concentration of Polatuzumab Vedotin

	Antibody-Conjugated Mono-Methyl Auristatin E (MMAE) (acMMAE)

End point description:

acMMAE is an analyte of polatuzumab vedotin. PK evaluable population included all participants who had at least one evaluable PK sample post dose for at least one analyte. Overall number analysed is the number of participants with data available for analysis. Number analysed is the number of participants with data available for analysis at the specified timepoint.Here, 9999= The data was not evaluable as the samples were below lower limit of quantification (BLLQ); 99999= Geometric coefficient of variation was not evaluable as the samples were BLLQ; 999999= Since only 1 participant was analysed, the geometric coefficient of variation was not evaluable;9999999= participants were not analysed for this PK endpoint at the given timepoint.

End point type	Secondary

End point timeframe:

Pre-dose and 0.5 hours post-dose on Day 1 of Cycles 1, 2 and 4; post-dose on Days 8 and 15 of Cycle 1; predose on Day 1 of Cycle 6 (1 cycle=21 days)

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: nanograms per milliliters (ng/mL)				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=7,3,3,3,9,8,40,3,6,8,39)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D1: 0.5 h Post dose(n=6,3,3,3,9,8,39,3,6,8,38)	131 (± 19054.2)	530 (± 22.2)	451 (± 48.0)	610 (± 3.4)
C1 D8: Dose (n=7,3,3,3,8,8,40,2,5,6,36)	19.1 (± 890.8)	57.0 (± 19.3)	9.87 (± 43972.4)	49.3 (± 33.6)
C1 D15: Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	6.67 (± 421.2)	22.9 (± 18.1)	4.56 (± 5235.8)	18.7 (± 24.2)
C2 D1: Predose (n=7,3,3,3,8,8,39,3,5,6,35)	3.69 (± 296.8)	12.6 (± 36.9)	3.25 (± 2446.9)	9.34 (± 44.7)
C2 D1: 0.5 h Post Dose(n=7,3,3,3,8,8,39,3,6,6,37)	527 (± 27.3)	594 (± 18.7)	602 (± 36.8)	555 (± 3.0)
C4 D1: Predose (n=7,3,2,3,8,7,37,3,2,4,30)	10.8 (± 69.4)	18.8 (± 24.9)	29.4 (± 10.1)	19.7 (± 8.2)
C4 D1: 0.5 h Post Dose (n=7,3,2,3,8,6,37,3,2,4,29)	491 (± 28.1)	587 (± 16.3)	768 (± 29.5)	620 (± 7.4)
C6 D1: Predose (n=7,3,2,3,8,7,33,2,1,3,24)	13.0 (± 58.5)	4.62 (± 5273.1)	23.5 (± 42.5)	20.5 (± 3.7)
Unscheduled Visit (n=2,0,0,0,0,0,2,0,0,0,0)	5.36 (± 99999)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	40	3
Units: nanograms per milliliters (ng/mL)				
geometric mean (geometric coefficient				

of variation)				
C1 D1: Predose(n=7,3,3,3,9,8,40,3,6,8,39)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D1: 0.5 h Post dose(n=6,3,3,3,9,8,39,3,6,8,38)	645 (± 24.6)	825 (± 20.8)	613 (± 38.2)	722 (± 25.3)
C1 D8: Dose (n=7,3,3,3,8,8,40,2,5,6,36)	58.0 (± 39.7)	88.9 (± 20.7)	41.0 (± 192.1)	45.6 (± 27.7)
C1 D15: Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	17.7 (± 56.9)	31.6 (± 15.3)	14.4 (± 176.9)	26.0 (± 69.8)
C2 D1: Predose (n=7,3,3,3,8,8,39,3,5,6,35)	8.27 (± 62.6)	16.7 (± 40.2)	7.71 (± 209.4)	14.9 (± 66.9)
C2 D1: 0.5 h Post Dose(n=7,3,3,3,8,8,39,3,6,6,37)	682 (± 24.0)	844 (± 19.7)	688 (± 20.7)	749 (± 23.0)
C4 D1: Predose (n=7,3,2,3,8,7,37,3,2,4,30)	23.4 (± 35.0)	27.5 (± 37.0)	21.5 (± 53.3)	24.8 (± 25.8)
C4 D1: 0.5 h Post Dose (n=7,3,2,3,8,6,37,3,2,4,29)	553 (± 90.9)	474 (± 299.3)	644 (± 66.8)	968 (± 33.7)
C6 D1: Predose (n=7,3,2,3,8,7,33,2,1,3,24)	28.6 (± 27.2)	27.3 (± 35.9)	25.2 (± 56.9)	24.3 (± 24.4)
Unscheduled Visit (n=2,0,0,0,0,0,2,0,0,0,0)	9999999 (± 9999999)	9999999 (± 9999999)	11.3 (± 99999)	9999999 (± 9999999)

End point values	DLBCL Dose Escalation: 1.8P+600V+37	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	8	39	
Units: nanograms per milliliters (ng/mL)				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=7,3,3,3,9,8,40,3,6,8,39)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	
C1 D1: 0.5 h Post dose(n=6,3,3,3,9,8,39,3,6,8,38)	628 (± 27.1)	683 (± 22.2)	481 (± 226.7)	
C1 D8: Dose (n=7,3,3,3,8,8,40,2,5,6,36)	50.8 (± 42.6)	77.0 (± 25.3)	57.9 (± 42.2)	
C1 D15: Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	19.8 (± 50.5)	30.2 (± 21.5)	22.3 (± 40.6)	
C2 D1: Predose (n=7,3,3,3,8,8,39,3,5,6,35)	8.94 (± 100.6)	14.8 (± 29.2)	13.1 (± 45.3)	
C2 D1: 0.5 h Post Dose(n=7,3,3,3,8,8,39,3,6,6,37)	341 (± 353.1)	748 (± 17.7)	628 (± 27.6)	
C4 D1: Predose (n=7,3,2,3,8,7,37,3,2,4,30)	8.16 (± 245.5)	30.1 (± 12.3)	22.2 (± 49.8)	
C4 D1: 0.5 h Post Dose (n=7,3,2,3,8,6,37,3,2,4,29)	722 (± 1.8)	775 (± 15.2)	680 (± 25.9)	
C6 D1: Predose (n=7,3,2,3,8,7,33,2,1,3,24)	3.73 (± 999999)	31.5 (± 46.0)	24.7 (± 54.4)	
Unscheduled Visit (n=2,0,0,0,0,0,2,0,0,0,0)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Concentration of Polatuzumab Vedotin Unconjugated MMAE

End point title	Observed Plasma Concentration of Polatuzumab Vedotin Unconjugated MMAE

End point description:

MMAE is an analyte of polatuzumab vedotin. PK evaluable population included all participants who had at least one evaluable PK sample post dose for at least one analyte. Overall number analysed is the number of participants with data available for analysis. Number analysed is the number of participants with data available for analysis at the specified timepoint.Here, 9999= The data was not evaluable as the samples were below lower limit of quantification (BLLQ); 99999= Geometric coefficient of variation was not evaluable as the samples were BLLQ; 999999= Since only 1 participant was analysed, the geometric coefficient of variation was not evaluable;9999999= participants were not analysed for this PK endpoint at the given timepoint.

End point type	Secondary

End point timeframe:

Pre-dose and 0.5 hours post-dose on Day 1 of Cycles 1, 2 and 4; post-dose on Days 8 and 15 of Cycle 1; predose on Day 1 of Cycle 6 (1 cycle=21 days)

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose (n=7,3,3,3,9,8,39,3,6,8,38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D1: 0.5 h Post Dose (n=6,3,3,3,9,8,40,3,6,8,38)	0.313 (± 725.2)	0.236 (± 31.1)	1.04 (± 575.7)	0.417 (± 60.3)
C1 D8: Post Dose (n=7,3,3,3,8,8,40,3,5,6,36)	1.14 (± 34.8)	57.5 (± 1.46)	1.57 (± 63.6)	1.06 (± 43.6)
C1 D15: Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	0.225 (± 87.4)	0.310 (± 60.2)	0.213 (± 174.3)	0.341 (± 55.9)
C2 D1: Predose (n=7,3,3,3,8,8,39,3,6,6,37)	0.0575 (± 117.0)	0.103 (± 47.1)	0.0565 (± 132.5)	0.0982 (± 75.3)
C2 D1: 0.5 h Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	0.152 (± 46.2)	0.184 (± 29.0)	0.399 (± 104.7)	0.175 (± 57.0)
C4 D1: Predose (n=7,3,2,3,8,8,36,3,2,4,30)	0.131 (± 58.2)	0.106 (± 48.3)	0.180 (± 62.4)	0.172 (± 46.8)
C4 D1: 0.5h Post Dose (n=7,3,2,3,8,7,37,3,2,4,29)	0.235 (± 84.2)	0.163 (± 50.6)	0.255 (± 48.6)	0.270 (± 31.6)
C6 D1: Predose (n=7,3,2,3,8,6,35,2,1,2,24	0.107 (± 73.4)	0.120 (± 62.3)	0.0715 (± 99999)	0.239 (± 17.2)
Unscheduled Visit (n=2,0,0,0,0,7,2,0,0,0,0)	0.0180 (± 99999)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+37

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	40	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose (n=7,3,3,3,9,8,39,3,6,8,38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1 D1: 0.5 h Post Dose (n=6,3,3,3,9,8,40,3,6,8,38)	0.507 (± 112.0)	9999 (± 9999)	0.441 (± 208.3)	0.249 (± 8.7)
C1 D8: Post Dose (n=7,3,3,3,8,8,40,3,5,6,36)	1.66 (± 69.9)	0.323 (± 79.3)	1.81 (± 65.3)	2.34 (± 54.7)
C1 D15: Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	0.461 (± 76.6)	2.26 (± 76.3)	0.444 (± 99.8)	0.675 (± 144.7)
C2 D1: Predose (n=7,3,3,3,8,8,39,3,6,6,37)	0.0866 (± 141.8)	0.688 (± 73.8)	0.113 (± 136.1)	0.221 (± 199.1)
C2 D1: 0.5 h Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	0.231 (± 76.5)	0.150 (± 41.9)	0.257 (± 63.8)	0.343 (± 122.0)
C4 D1: Predose (n=7,3,2,3,8,8,36,3,2,4,30)	0.155 (± 46.5)	0.263 (± 46.5)	0.167 (± 81.0)	0.238 (± 75.5)
C4 D1: 0.5h Post Dose (n=7,3,2,3,8,7,37,3,2,4,29)	0.209 (± 42.0)	0.206 (± 36.2)	0.260 (± 56.2)	0.331 (± 77.4)
C6 D1: Predose (n=7,3,2,3,8,6,35,2,1,2,24	0.189 (± 37.2)	0.289 (± 55.2)	0.162 (± 94.9)	0.197 (± 275.2)
Unscheduled Visit (n=2,0,0,0,0,7,2,0,0,0,0)	9999999 (± 9999999)	0.196 (± 89.0)	0.0852 (± 99999)	9999999 (± 9999999)

End point values	DLBCL Dose Escalation: 1.8P+600V+37	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	8	38	
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose (n=7,3,3,3,9,8,39,3,6,8,38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	
C1 D1: 0.5 h Post Dose (n=6,3,3,3,9,8,40,3,6,8,38)	0.390 (± 89.0)	0.262 (± 61.9)	0.263 (± 90.8)	
C1 D8: Post Dose (n=7,3,3,3,8,8,40,3,5,6,36)	2.77 (± 63.1)	2.51 (± 96.3)	2.51 (± 65.1)	
C1 D15: Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	0.927 (± 89.8)	0.778 (± 77.9)	0.723 (± 63.3)	
C2 D1: Predose (n=7,3,3,3,8,8,39,3,6,6,37)	0.311 (± 76.4)	0.266 (± 161.7)	0.227 (± 66.1)	
C2 D1: 0.5 h Post Dose (n=7,3,3,3,8,8,39,3,6,6,37)	0.564 (± 76.4)	0.407 (± 116.2)	0.322 (± 55.9)	
C4 D1: Predose (n=7,3,2,3,8,8,36,3,2,4,30)	0.459 (± 103.4)	0.295 (± 90.5)	0.220 (± 72.7)	
C4 D1: 0.5h Post Dose (n=7,3,2,3,8,7,37,3,2,4,29)	0.565 (± 107.5)	0.364 (± 65.6)	0.311 (± 57.7)	
C6 D1: Predose (n=7,3,2,3,8,6,35,2,1,2,24	0.795 (± 999999)	0.334 (± 62.1)	0.211 (± 93.8)	
Unscheduled Visit (n=2,0,0,0,0,7,2,0,0,0,0)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Observed Plasma Venetoclax Concentration

End point title	Observed Plasma Venetoclax Concentration

End point description:

1 cycle = 21 days. PK evaluable population included all participants who had at least one evaluable PK sample post dose for at least one analyte. Overall number analysed is the number of participants with data available for analysis. Number analysed is the number of participants with data available for analysis at the specified timepoint.Here, 9999= The data was not evaluable as the samples were below lower limit of quantification (BLLQ); 99999= Geometric coefficient of variation was not evaluable as the samples were BLLQ; 999999= Since only 1 participant was analysed, the geometric coefficient of variation was not evaluable; 9999999= participants were not analysed for this PK endpoint at the given timepoint.

End point type	Secondary

End point timeframe:

Pre-dose and 4 hours post-dose on Day 1 Cycle 1, pre-dose & 2, 4, 6, & 8 hours post-dose on Day 1 Cycle 2, pre-dose & 4hours post-dose on Day 1 Cycle 4 & pre-dose on Day 1 Cycle 6; (1 cycle = 21 days)

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=0,0,0,0,0,0,0,0,0,0,2)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)
C1 D1: PostDose(n=6,3,3,3,9,8,41,3,6,7,40)	0.624 (± 94.6)	0.247 (± 162.1)	0.108 (± 53.3)	0.244 (± 149.1)
C2 D1: Predose(n=7,3,3,3,8,8,39,3,6,6,35)	0.336 (± 99.3)	0.347 (± 144.3)	0.453 (± 71.9)	0.943 (± 28.5)
C2 D1: 2 h PostDose(n=7,3,2,2,7,6,1,3,5,5,1)	0.532 (± 119.2)	0.306 (± 107.3)	0.351 (± 129.3)	0.822 (± 54.8)
C2 D1: 4 h PostDose(n=7,3,3,3,8,7,39,3,6,6,39)	1.12 (± 102.2)	0.572 (± 49.1)	0.548 (± 51.0)	1.31 (± 22.5)
C2 D1: 6 h PostDose(n=7,3,2,2,7,6,1,3,5,5,1)	1.38 (± 83.4)	0.933 (± 72.1)	1.21 (± 24.8)	1.99 (± 5.7)
C2 D1: 8 h PostDose(n=7,3,2,2,6,5,1,3,4,4,1)	1.40 (± 74.9)	0.803 (± 76.7)	1.45 (± 32.3)	2.24 (± 18.4)
C4 D1: Predose(n=7,3,2,3,8,7,36,3,2,4,30)	0.259 (± 157.2)	0.0344 (± 15072.4)	0.302 (± 1.2)	1.12 (± 40.2)
C4 D1: PostDose(n=0,0,0,0,0,0,0,0,0,0,2)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)

C6 D1: Predose(n=7,3,2,3,8,7,34,2,1,3,24)	0.252 (± 95.0)	0.277 (± 178.7)	0.0177 (± 99999)	1.24 (± 56.1)

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	41	3
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=0,0,0,0,0,0,0,0,0,0,2)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)
C1 D1: PostDose(n=6,3,3,3,9,8,41,3,6,7,40)	0.796 (± 86.5)	0.811 (± 310.3)	0.964 (± 69.2)	0.503 (± 47.9)
C2 D1: Predose(n=7,3,3,3,8,8,39,3,6,6,35)	0.298 (± 2853.1)	0.282 (± 498.3)	0.555 (± 1134.4)	0.529 (± 135.6)
C2 D1: 2 h PostDose(n=7,3,2,2,7,6,1,3,5,5,1)	0.769 (± 131.0)	0.921 (± 74.0)	2.69 (± 999999)	0.632 (± 90.1)
C2 D1: 4 h PostDose(n=7,3,3,3,8,7,39,3,6,6,39)	1.65 (± 69.4)	2.04 (± 39.2)	1.99 (± 59.0)	0.830 (± 75.3)
C2 D1: 6 h PostDose(n=7,3,2,2,7,6,1,3,5,5,1)	2.15 (± 51.9)	2.55 (± 28.0)	4.82 (± 999999)	0.870 (± 98.1)
C2 D1: 8 h PostDose(n=7,3,2,2,6,5,1,3,4,4,1)	2.46 (± 59.8)	2.53 (± 32.7)	3.02 (± 999999)	0.886 (± 87.6)
C4 D1: Predose(n=7,3,2,3,8,7,36,3,2,4,30)	0.551 (± 98.4)	0.304 (± 1059.7)	0.561 (± 401.2)	0.0581 (± 1105.7)
C4 D1: PostDose(n=0,0,0,0,0,0,0,0,0,0,2)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)	9999999 (± 9999999)
C6 D1: Predose(n=7,3,2,3,8,7,34,2,1,3,24)	0.595 (± 95.4)	0.0266 (± 26843.8)	0.509 (± 496.6)	0.175 (± 187.9)

End point values	DLBCL Dose Escalation: 1.8P+600V+37	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	40	
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C1 D1: Predose(n=0,0,0,0,0,0,0,0,0,0,2)	9999999 (± 9999999)	9999999 (± 9999999)	9999 (± 9999)	
C1 D1: PostDose(n=6,3,3,3,9,8,41,3,6,7,40)	0.915 (± 47.4)	1.21 (± 103.4)	0.841 (± 94.8)	
C2 D1: Predose(n=7,3,3,3,8,8,39,3,6,6,35)	0.952 (± 139.7)	0.852 (± 1812.3)	0.329 (± 1047.7)	
C2 D1: 2 h PostDose(n=7,3,2,2,7,6,1,3,5,5,1)	1.08 (± 82.0)	1.01 (± 464.7)	999999 (± 5.13)	
C2 D1: 4 h PostDose(n=7,3,3,3,8,7,39,3,6,6,39)	1.49 (± 43.1)	2.03 (± 131.4)	1.50 (± 74.5)	
C2 D1: 6 h PostDose(n=7,3,2,2,7,6,1,3,5,5,1)	1.96 (± 57.5)	2.74 (± 117.9)	5.95 (± 999999)	
C2 D1: 8 h PostDose(n=7,3,2,2,6,5,1,3,4,4,1)	1.88 (± 70.8)	2.85 (± 94.7)	6.66 (± 999999)	

C4 D1: Predose(n=7,3,2,3,8,7,36,3,2,4,30)	0.933 (± 74.2)	0.826 (± 311.3)	0.337 (± 1043.6)	
C4 D1: PostDose(n=0,0,0,0,0,0,0,0,0,0,2)	9999999 (± 9999999)	9999999 (± 9999999)	1.04 (± 8.4)	
C6 D1: Predose(n=7,3,2,3,8,7,34,2,1,3,24)	1.90 (± 999999)	0.0772 (± 101668.3)	0.365 (± 780.9)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Participants with Human Anti-Human Antibodies (HAHAs) to Obinutuzumab[23]

End point description:

The number of participants with positive results for HAHAs, also called anti-drug antibodies (ADAs) against obinutuzumab at baseline & at any of the post-baseline assessment time-points were reported. Number of participants positive for Treatment Emergent ADA = the number of post-baseline evaluable participants determined to have treatment induced ADA or treatment-enhanced ADA during study period. Treatment-induced ADA = negative or missing baseline ADA result at least one positive post-baseline ADA result. Treatment-enhanced ADA = a participant with positive ADA result at baseline who has one or more post-baseline titer results that are at least 0.60 titer unit (t.u.) greater than baseline. The immunogenicity population included participants with at least one predose and one postdose HAHA or ATA sample. Overall number analysed=number of participants with data available for analysis. Number analysed=number of participants with data available for analysis at a specified timepoint.

End point type	Secondary

End point timeframe:

Baseline up to approximately 2 years after last dose (up to approximately 52 months)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is reporting data for all arms that received obinutuzumab. Hence, data is reported for FL cohorts only.

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: participants				
Baseline prev. of ADAs (n=3,7,3,2,9,7,39)	0	0	0	0
Post baseline inc. of ADAs (n=3,7,3,3,8,8,39)	0	0	0	0

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	8	39	

Units: participants				
Baseline prev. of ADAs (n=3,7,3,2,9,7,39)	0	0	0	
Post baseline inc. of ADAs (n=3,7,3,3,8,8,39)	0	0	0	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The number of participants with positive results for ATAs, also called ADAs against polatuzumab vedotin at baseline and at any of the post-baseline assessment time-points were reported. Number of participants positive for Treatment Emergent ADA = the number of post-baseline evaluable participants determined to have treatment induced ADA or treatment-enhanced ADA during the study period. Treatment-induced ADA = negative or missing baseline ADA result(s) and at least one positive post-baseline ADA result. Treatment-enhanced ADA = a participant with positive ADA result at baseline who has one or more post-baseline titer results that are at least 0.60 t.u. greater than the baseline titer result. Immunogenicity population included participants with at least one predose and one postdose ATA assessment, with participants grouped according to histology. Number analysed=number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Baseline up to 1 year post last dose (up to approximately 16 months)

End point values	FL Dose Escalation: 1.4P+400V+1000G	FL Dose Escalation: 1.4P+200V+1000G	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: participants				
Baseline ADAs (n=3,6,3,3,9,7,3,6,8,41,40)	1	0	0	0
Post baseline ADAs (n=3,7,3,3,9,8,3,6,7,41,39)	1	0	0	0

End point values	FL Dose Escalation: 1.8P+600V+1000G	FL Dose Escalation: 1.8P+800V+1000G	FL: Dose Expansion: 1.8P+800V+1000G	DLBCL: Dose Escalation: 1.8P+400V+37
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	41	3
Units: participants				
Baseline ADAs (n=3,6,3,3,9,7,3,6,8,41,40)	0	0	0	0

Post baseline ADAs (n=3,7,3,3,9,8,3,6,7,41,39)	0	0	0	0

End point values	DLBCL Dose Escalation: 1.8P+600V+37	DLBCL Dose Escalation: 1.8P+800V+37	DLBCL Dose Expansion: 1.8P+800V+37	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	8	40	
Units: participants				
Baseline ADAs (n=3,6,3,3,9,7,3,6,8,41,40)	0	0	0	
Post baseline ADAs (n=3,7,3,3,9,8,3,6,7,41,39)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

FL cohorts: From study start to 24 months after last dose of study drug (approximately 42 months); DLBCL cohorts: From study start to 3 months after last dose of study drug (approximately 21 months)

Adverse event reporting additional description:

Safety-evaluable population included all participants who received at least one dose of any component of the combination.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25

Reporting groups

Reporting group title	DLBCL: Dose Escalation: 1.8P+400V+375R

Reporting group description:

Participants received venetoclax, 400 mg, orally, once daily (QD) on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved complete response (CR) or partial response (PR) at end of induction (EOI) received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 400 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Escalation: 1.8P+600V+375R

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 600 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Escalation: 1.8P+800V+375R

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	DLBCL Dose Expansion: 1.8P+800V+375R

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with rituximab, 375 mg/m^2, IV infusion, on Day 1 of Cycles 1-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR or PR at EOI received consolidation treatment until disease progression or unacceptable toxicity for up to 8 months. During consolidation treatment participants received venetoclax, 800 mg, QD, for up to 8 months and rituximab, 375 mg/m^2 on Day 1 of every other month (1 month=28 days) starting from Month 2 up to 8 months.

Reporting group title	FL Dose Escalation: 1.4P+400V+1000G

Reporting group description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day

1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL: Dose Expansion: 1.8P+800V+1000G

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+400V+1000G

Reporting group description:

Participants received venetoclax, 400 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 400 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.4P+600V+1000G

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.8P+600V+1000G

Reporting group description:

Participants received venetoclax, 600 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 600 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months

Reporting group title	FL Dose Escalation: 1.8P+800V+1000G

Reporting group description:

Participants received venetoclax, 800 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.8 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 800 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Reporting group title	FL Dose Escalation: 1.4P+200V+1000G

Reporting group description:

Participants received venetoclax, 200 mg, orally, QD on Days 1-21 of Cycles 1-6 (1 cycle=21 days) along with obinutuzumab, 1000 mg, IV infusion, on Days 1, 8 and 15 of Cycle 1 and thereafter on Day 1 of Cycles 2-6 and polatuzumab vedotin, 1.4 mg/kg, IV infusion, on Day 1 of Cycles 1-6 as induction treatment. Thereafter participants who achieved CR, PR, or SD at EOI received maintenance treatment until disease progression or unacceptable toxicity for up to 24 months. During maintenance treatment participants received venetoclax, 200 mg, QD, for up to 8 months and obinutuzumab, 1000 mg on Day 1 of every other month (1 month=28 days) starting from Month 2 for up to 24 months.

Serious adverse events	DLBCL: Dose Escalation: 1.8P+400V+375R	DLBCL Dose Escalation: 1.8P+600V+375R	DLBCL Dose Escalation: 1.8P+800V+375R
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 6 (66.67%)	2 / 8 (25.00%)
number of deaths (all causes)	0	4	6
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
PYREXIA			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 8 (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
Respiratory, thoracic and mediastinal disorders			

ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIECTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
PNEUMONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Product issues			
DEVICE LEAKAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ULNA FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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			
CARDIAC FAILURE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 CONGESTIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIOMYOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
ENCEPHALOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
NEUTROPENIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETINAL TEAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
VOMITING			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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			
LIVER INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (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
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

PNEUMONIA VIRAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 DEVICE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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			
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

HYPERVOLAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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	DLBCL Dose Expansion: 1.8P+800V+375R	FL Dose Escalation: 1.4P+400V+1000G	FL: Dose Expansion: 1.8P+800V+1000G
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 40 (30.00%)	4 / 7 (57.14%)	14 / 41 (34.15%)
number of deaths (all causes)	26	3	8
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCOSAL INFLAMMATION			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIECTASIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			

subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
DEVICE LEAKAGE			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			

subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 0	1 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ULNA FRACTURE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIOMYOPATHY			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
ENCEPHALOPATHY			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences causally related to treatment / all	0 / 2	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETINAL TEAR			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CONSTIPATION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
LIVER INJURY			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
BRONCHITIS			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
COVID-19			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (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
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC SEPSIS			

subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 40 (0.00%)	2 / 7 (28.57%)	3 / 41 (7.32%)
occurrences causally related to treatment / all	0 / 0	0 / 8	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
PNEUMONIA VIRAL			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVOLAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G	FL Dose Escalation: 1.8P+600V+1000G
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 9 (22.22%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
DEEP VEIN THROMBOSIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
ADVERSE DRUG REACTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (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
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIECTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
DEVICE LEAKAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ALANINE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (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
ULNA FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
CARDIAC FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 CONGESTIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CARDIOMYOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
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			
ENCEPHALOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETINAL TEAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
LIVER INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA VIRAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 DEVICE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVOLAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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	FL Dose Escalation: 1.8P+800V+1000G	FL Dose Escalation: 1.4P+200V+1000G	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	1 / 3 (33.33%)	
number of deaths (all causes)	1	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHIECTASIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOXIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			

DEVICE LEAKAGE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIP FRACTURE			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ULNA FRACTURE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
CARDIAC FAILURE			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIOMYOPATHY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
ENCEPHALOPATHY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEBRILE NEUTROPENIA			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RETINAL TEAR			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONSTIPATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
LIVER INJURY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOCALISED INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

PNEUMONIA VIRAL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SINUSITIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSEUDOMONAS INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

HYPERVOLAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	DLBCL: Dose Escalation: 1.8P+400V+375R	DLBCL Dose Escalation: 1.8P+600V+375R	DLBCL Dose Escalation: 1.8P+800V+375R
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	7 / 8 (87.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OCULAR SURFACE SQUAMOUS NEOPLASIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OCULAR MELANOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SKIN CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SKIN PAPILLOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
FLUSHING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
POOR VENOUS ACCESS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
TOOTH EXTRACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			

subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences (all)	1	1	3
EARLY SATIETY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
CHILLS			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
MALAISE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
INJECTION SITE EXTRAVASATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OEDEMA MUCOSAL			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	2 / 8 (25.00%)
occurrences (all)	1	3	2
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
ANISOMASTIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
PROSTATIC DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ENDOMETRIAL THICKENING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
BREAST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
BREAST CYST			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
DRY THROAT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ATELECTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
HAEMOPTYSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
HICCUPS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
PULMONARY CONGESTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
PULMONARY MASS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
THROAT IRRITATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SINUS PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

RHINITIS ALLERGIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
AGITATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
HALLUCINATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
CONFUSIONAL STATE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
LIBIDO DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
AMYLASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
BLOOD CALCIUM INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD IMMUNOGLOBULIN G DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS DECREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INFLUENZA A VIRUS TEST POSITIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PROTEIN TOTAL DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OCCULT BLOOD POSITIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	2 / 8 (25.00%)
occurrences (all)	0	2	2
URINARY CASTS PRESENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RED BLOOD CELLS URINE POSITIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PROTEIN URINE PRESENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
LIPASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
INCISIONAL HERNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
HAND FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
PERIORBITAL HAEMATOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LIGAMENT SPRAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	3 / 8 (37.50%)
occurrences (all)	2	0	4
SKIN LACERATION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS SITE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SKIN WOUND			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	4
SINUS BRADYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
PALPITATIONS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CORONARY ARTERY OCCLUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
HEADACHE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
DYSGEUSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
APHASIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
MIGRAINE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
HYPOAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
NEURALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
NEUROPATHY PERIPHERAL			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
RESTING TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
SOMNOLENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
TASTE DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	3 / 8 (37.50%)
occurrences (all)	1	3	4
PANCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	5 / 8 (62.50%)
occurrences (all)	5	7	7
LYMPHADENOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERGAMMAGLOBULINAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

THROMBOCYTOPENIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
LEUKOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
OTORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
DEAFNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DIPLOPIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
VISION BLURRED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
SCLERAL HYPERAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
DRY MOUTH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
DIARRHOEA			
subjects affected / exposed	3 / 3 (100.00%)	1 / 6 (16.67%)	5 / 8 (62.50%)
occurrences (all)	4	1	8
DENTAL CARIES			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	2	2
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
ABDOMINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences (all)	0	2	3
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

DYSPEPSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
GASTROINTESTINAL DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
DYSPHAGIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
FAECES SOFT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ORAL DISCHARGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ODYNOPHAGIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	3 / 3 (100.00%)	3 / 6 (50.00%)	1 / 8 (12.50%)
occurrences (all)	4	4	1
MUCOUS STOOLS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
ORAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	2 / 3 (66.67%)	3 / 6 (50.00%)	4 / 8 (50.00%)
occurrences (all)	3	3	11
TOOTHACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CHOLELITHIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACTINIC KERATOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COLD SWEAT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
ECCHYMOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERKERATOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INGROWING NAIL			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MILIARIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ONYCHOMADESIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
SKIN HYPERTROPHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SOLAR LENTIGO			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
POLLAKIURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

HAEMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RENAL IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
URINE ABNORMALITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
ARTHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ARTHRALGIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
BONE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
JOINT STIFFNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
GROIN PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
MYALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PAIN IN JAW			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PLANTAR FASCIITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
OSTEOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OSTEOARTHRITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
CANDIDA INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
CAMPYLOBACTER INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BACTERIAL DISEASE CARRIER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CHRONIC SINUSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

GASTROENTERITIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
OTITIS MEDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION ENTEROCOCCAL			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences (all)	0	1	4
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	4 / 8 (50.00%)
occurrences (all)	1	3	5
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
HYPERURICAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
GOUT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	1 / 8 (12.50%)
occurrences (all)	0	4	1
HYPOKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	4 / 6 (66.67%)	3 / 8 (37.50%)
occurrences (all)	0	4	3
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DEFICIENCY			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	DLBCL Dose Expansion: 1.8P+800V+375R	FL Dose Escalation: 1.4P+400V+1000G	FL: Dose Expansion: 1.8P+800V+1000G
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 40 (95.00%)	7 / 7 (100.00%)	41 / 41 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
OCULAR SURFACE SQUAMOUS NEOPLASIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
OCULAR MELANOMA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SKIN CANCER			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SKIN PAPILLOMA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	9
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1

POOR VENOUS ACCESS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	1	0	3
HYPERTENSION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	1	0	6
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Surgical and medical procedures			
TOOTH EXTRACTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	10 / 40 (25.00%)	5 / 7 (71.43%)	13 / 41 (31.71%)
occurrences (all)	10	7	14
EARLY SATIETY			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	3 / 40 (7.50%)	2 / 7 (28.57%)	3 / 41 (7.32%)
occurrences (all)	3	3	6
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	5 / 41 (12.20%)
occurrences (all)	0	0	6
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
MALAISE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
INJECTION SITE EXTRAVASATION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	4 / 41 (9.76%)
occurrences (all)	0	0	4
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	4 / 41 (9.76%)
occurrences (all)	2	0	4
OEDEMA MUCOSAL			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
PYREXIA			
subjects affected / exposed	6 / 40 (15.00%)	1 / 7 (14.29%)	5 / 41 (12.20%)
occurrences (all)	7	1	5
Immune system disorders			

SEASONAL ALLERGY			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	3 / 41 (7.32%)
occurrences (all)	1	1	3
Reproductive system and breast disorders			
ANISOMASTIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PROSTATIC DISORDER			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ENDOMETRIAL THICKENING			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BREAST CYST			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	0	3	1
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0

COUGH			
subjects affected / exposed	9 / 40 (22.50%)	3 / 7 (42.86%)	11 / 41 (26.83%)
occurrences (all)	11	8	14
DRY THROAT			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ATELECTASIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	1	0	3
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	4 / 40 (10.00%)	0 / 7 (0.00%)	6 / 41 (14.63%)
occurrences (all)	5	0	7
HICCUPS			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
NASAL CONGESTION			
subjects affected / exposed	0 / 40 (0.00%)	2 / 7 (28.57%)	3 / 41 (7.32%)
occurrences (all)	0	2	5
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	5 / 41 (12.20%)
occurrences (all)	1	0	7

PRODUCTIVE COUGH			
subjects affected / exposed	4 / 40 (10.00%)	1 / 7 (14.29%)	3 / 41 (7.32%)
occurrences (all)	5	1	4
PULMONARY CONGESTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PULMONARY MASS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFLAMMATION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
THROAT IRRITATION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
SINUS CONGESTION			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
SINUS PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	1	1	2
WHEEZING			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 40 (0.00%)	2 / 7 (28.57%)	2 / 41 (4.88%)
occurrences (all)	0	2	2
Psychiatric disorders			

INSOMNIA			
subjects affected / exposed	4 / 40 (10.00%)	2 / 7 (28.57%)	6 / 41 (14.63%)
occurrences (all)	4	2	7
AGITATION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HALLUCINATION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
DEPRESSION			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
CONFUSIONAL STATE			
subjects affected / exposed	3 / 40 (7.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
LIBIDO DECREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	2 / 7 (28.57%)	4 / 41 (9.76%)
occurrences (all)	0	2	9
AMYLASE INCREASED			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	3 / 41 (7.32%)
occurrences (all)	0	1	4
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
BLOOD CALCIUM DECREASED			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	2
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BLOOD CALCIUM INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN DECREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
BLOOD IMMUNOGLOBULIN G DECREASED			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	2 / 41 (4.88%)
occurrences (all)	0	1	2
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	3	0	2
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
INFLUENZA A VIRUS TEST POSITIVE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PROTEIN TOTAL DECREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
OCCULT BLOOD POSITIVE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	3 / 40 (7.50%)	1 / 7 (14.29%)	7 / 41 (17.07%)
occurrences (all)	3	1	7
URINARY CASTS PRESENT			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
RED BLOOD CELLS URINE POSITIVE			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
PROTEIN URINE PRESENT			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
INCISIONAL HERNIA			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
FALL			

subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	2	0	4
HAND FRACTURE			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
HIP FRACTURE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
RIB FRACTURE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL HAEMATOMA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LIGAMENT SPRAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	2 / 40 (5.00%)	2 / 7 (28.57%)	13 / 41 (31.71%)
occurrences (all)	2	2	14
SKIN LACERATION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS SITE PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
TOOTH FRACTURE			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	1	0	2
SUNBURN			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
SKIN WOUND			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
TACHYCARDIA			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	2
SINUS BRADYCARDIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
PALPITATIONS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
CORONARY ARTERY OCCLUSION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	3 / 40 (7.50%)	2 / 7 (28.57%)	8 / 41 (19.51%)
occurrences (all)	3	3	15
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	4 / 40 (10.00%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	5	0	4
DYSGEUSIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
APHASIA			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
HYPOAESTHESIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
NEURALGIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	6 / 41 (14.63%)
occurrences (all)	1	1	6
PARAESTHESIA			
subjects affected / exposed	3 / 40 (7.50%)	1 / 7 (14.29%)	5 / 41 (12.20%)
occurrences (all)	4	2	5
NEUROPATHY PERIPHERAL			
subjects affected / exposed	5 / 40 (12.50%)	1 / 7 (14.29%)	11 / 41 (26.83%)
occurrences (all)	5	1	11
RESTING TREMOR			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
SOMNOLENCE			
subjects affected / exposed	3 / 40 (7.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
TASTE DISORDER			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	4
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	5 / 40 (12.50%)	1 / 7 (14.29%)	7 / 41 (17.07%)
occurrences (all)	9	1	13
PANCYTOPENIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	20 / 40 (50.00%)	2 / 7 (28.57%)	17 / 41 (41.46%)
occurrences (all)	64	3	46
LYMPHADENOPATHY			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPERGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	6 / 40 (15.00%)	3 / 7 (42.86%)	12 / 41 (29.27%)
occurrences (all)	8	4	37
LEUKOPENIA			
subjects affected / exposed	3 / 40 (7.50%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	9	1	4
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
OTORRHOEA			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
DEAFNESS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Eye disorders			
CATARACT			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
DIPLOPIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SCLERAL HYPERAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0

Gastrointestinal disorders			
DRY MOUTH			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
DIARRHOEA			
subjects affected / exposed	16 / 40 (40.00%)	3 / 7 (42.86%)	20 / 41 (48.78%)
occurrences (all)	20	6	42
DENTAL CARIES			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
CONSTIPATION			
subjects affected / exposed	6 / 40 (15.00%)	2 / 7 (28.57%)	10 / 41 (24.39%)
occurrences (all)	6	3	14
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	5 / 41 (12.20%)
occurrences (all)	1	1	6
ABDOMINAL DISTENSION			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	7
DYSPEPSIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	6 / 41 (14.63%)
occurrences (all)	1	0	8
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
GASTROINTESTINAL DISORDER			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
FLATULENCE			

subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	2
DYSPHAGIA			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
FAECES DISCOLOURED			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
FAECES SOFT			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
HAEMORRHOIDS			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	0	1	2
ORAL DISCHARGE			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
ODYNOPHAGIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	14 / 40 (35.00%)	2 / 7 (28.57%)	23 / 41 (56.10%)
occurrences (all)	15	3	35
MUCOUS STOOLS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0

ORAL PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	8 / 40 (20.00%)	2 / 7 (28.57%)	11 / 41 (26.83%)
occurrences (all)	8	3	17
TOOTHACHE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
CHOLELITHIASIS			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACTINIC KERATOSIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	3 / 41 (7.32%)
occurrences (all)	1	1	3
COLD SWEAT			

subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	3 / 40 (7.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
ECCHYMOSIS			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
ECZEMA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
ERYTHEMA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
HYPERKERATOSIS			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
INGROWING NAIL			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MILIARIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
ONYCHOMADESIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PRURITUS			

subjects affected / exposed	3 / 40 (7.50%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	3	0	2
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	4 / 41 (9.76%)
occurrences (all)	2	0	7
SKIN HYPERTROPHY			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
SOLAR LENTIGO			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
POLLAKIURIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
HAEMATURIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
RENAL IMPAIRMENT			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
URINE ABNORMALITY			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0

URINARY TRACT PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
subjects affected / exposed	3 / 40 (7.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	3 / 40 (7.50%)	1 / 7 (14.29%)	8 / 41 (19.51%)
occurrences (all)	3	1	8
ARTHRITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
ARTHRALGIA			
subjects affected / exposed	4 / 40 (10.00%)	2 / 7 (28.57%)	7 / 41 (17.07%)
occurrences (all)	5	3	8
BONE PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
MUSCLE SPASMS			

subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
JOINT STIFFNESS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	2
MYALGIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PAIN IN JAW			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
PLANTAR FASCIITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	4 / 41 (9.76%)
occurrences (all)	1	1	8
OSTEOPENIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
OSTEOARTHRITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
CANDIDA INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CAMPYLOBACTER INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	1 / 41 (2.44%)
occurrences (all)	1	12	2

BACTERIAL DISEASE CARRIER			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CHRONIC SINUSITIS			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	2
CONJUNCTIVITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	2
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
LOWER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	1	0	5
NASOPHARYNGITIS			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	2	0	4
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	1 / 40 (2.50%)	2 / 7 (28.57%)	1 / 41 (2.44%)
occurrences (all)	1	2	1
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	2
RHINITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	3 / 41 (7.32%)
occurrences (all)	0	2	3
SINUSITIS			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	3
SKIN INFECTION			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
PNEUMONIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
VULVOVAGINAL MYCOTIC			

INFECTION			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION ENTEROCOCCAL			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	3 / 41 (7.32%)
occurrences (all)	2	1	4
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 40 (7.50%)	4 / 7 (57.14%)	11 / 41 (26.83%)
occurrences (all)	3	4	18
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	6 / 40 (15.00%)	0 / 7 (0.00%)	5 / 41 (12.20%)
occurrences (all)	7	0	6
DEHYDRATION			
subjects affected / exposed	3 / 40 (7.50%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
HYPERURICAEMIA			
subjects affected / exposed	3 / 40 (7.50%)	0 / 7 (0.00%)	3 / 41 (7.32%)
occurrences (all)	3	0	3
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	2 / 41 (4.88%)
occurrences (all)	0	1	3
HYPERGLYCAEMIA			
subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	4 / 41 (9.76%)
occurrences (all)	2	0	4
HYPERCALCAEMIA			

subjects affected / exposed	2 / 40 (5.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
GOUT			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 40 (2.50%)	0 / 7 (0.00%)	4 / 41 (9.76%)
occurrences (all)	1	0	8
HYPONATRAEMIA			
subjects affected / exposed	0 / 40 (0.00%)	0 / 7 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	2
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 40 (2.50%)	1 / 7 (14.29%)	2 / 41 (4.88%)
occurrences (all)	1	1	2
HYPOKALAEMIA			
subjects affected / exposed	4 / 40 (10.00%)	2 / 7 (28.57%)	4 / 41 (9.76%)
occurrences (all)	5	2	5
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 40 (0.00%)	1 / 7 (14.29%)	0 / 41 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	FL Dose Escalation: 1.8P+400V+1000G	FL Dose Escalation: 1.4P+600V+1000G	FL Dose Escalation: 1.8P+600V+1000G
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
OCULAR SURFACE SQUAMOUS NEOPLASIA			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
OCULAR MELANOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
SKIN CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SKIN PAPILLOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
FLUSHING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
POOR VENOUS ACCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Surgical and medical procedures			
TOOTH EXTRACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
ASTHENIA			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
CHEST DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE BRUISING			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
FATIGUE			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	2	2	2
EARLY SATIETY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
MALAISE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE EXTRAVASATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
OEDEMA MUCOSAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
ANISOMASTIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PROSTATIC DISORDER			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
ENDOMETRIAL THICKENING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BREAST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BREAST CYST			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 9 (33.33%)
occurrences (all)	3	1	3
DRY THROAT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ATELECTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

EPISTAXIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	4
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
PULMONARY CONGESTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PULMONARY MASS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFLAMMATION			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
THROAT IRRITATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
SINUS PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
AGITATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HALLUCINATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
LIBIDO DECREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
AMYLASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD CALCIUM DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
BLOOD CALCIUM INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

BLOOD FIBRINOGEN DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD IMMUNOGLOBULIN G DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
BLOOD PHOSPHORUS DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
INFLUENZA A VIRUS TEST POSITIVE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
PROTEIN TOTAL DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
OCCULT BLOOD POSITIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
WEIGHT DECREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
URINARY CASTS PRESENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RED BLOOD CELLS URINE POSITIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PROTEIN URINE PRESENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
INCISIONAL HERNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	3
HAND FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HIP FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RIB FRACTURE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL HAEMATOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
LIGAMENT SPRAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	4 / 9 (44.44%)
occurrences (all)	3	0	4
SKIN LACERATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS SITE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SKIN WOUND			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

SINUS BRADYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
CORONARY ARTERY OCCLUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
DIZZINESS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
APHASIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
LETHARGY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
NEURALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
NEUROPATHY PERIPHERAL			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	2	2	2
RESTING TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
SCIATICA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
PANCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

NEUTROPENIA			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	4 / 9 (44.44%)
occurrences (all)	2	5	17
LYMPHADENOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
HYPERGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
LEUKOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
OTORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
EAR PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
DEAFNESS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
DIPLOPIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SCLERAL HYPERAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
DRY MOUTH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
DIARRHOEA			
subjects affected / exposed	3 / 3 (100.00%)	2 / 3 (66.67%)	5 / 9 (55.56%)
occurrences (all)	7	2	8
DENTAL CARIES			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
DYSPEPSIA			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
FAECES SOFT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
HAEMORRHOIDS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ORAL DISCHARGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ODYNOPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	2	1	2
MUCOUS STOOLS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	1 / 9 (11.11%)
occurrences (all)	2	3	2
TOOTHACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
CHOLELITHIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACTINIC KERATOSIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
ALOPECIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
COLD SWEAT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
DRY SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ECZEMA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPERKERATOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
INGROWING NAIL			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
MILIARIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
ONYCHOMADESIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	3
SKIN HYPERTROPHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SOLAR LENTIGO			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Renal and urinary disorders			
POLLAKIURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
HAEMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
RENAL IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
URINE ABNORMALITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
URINARY INCONTINENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
ARTHRITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
ARTHRALGIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
BONE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
FLANK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
JOINT STIFFNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
MYALGIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
PAIN IN JAW			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
PLANTAR FASCIITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
OSTEOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
OSTEOARTHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Infections and infestations			
CANDIDA INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
CAMPYLOBACTER INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
BACTERIAL DISEASE CARRIER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
CHRONIC SINUSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVITIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	3	1	1
SKIN INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION ENTEROCOCCAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	4
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	2 / 9 (22.22%)
occurrences (all)	2	2	2
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
HYPOCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
GOUT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	2

HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	FL Dose Escalation: 1.8P+800V+1000G	FL Dose Escalation: 1.4P+200V+1000G	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	3 / 3 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
OCULAR SURFACE SQUAMOUS NEOPLASIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
OCULAR MELANOMA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
SKIN CANCER			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
SKIN PAPILLOMA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
SQUAMOUS CELL CARCINOMA			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
FLUSHING			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
POOR VENOUS ACCESS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPOTENSION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPERTENSION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
TOOTH EXTRACTION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
ASTHENIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CHEST DISCOMFORT			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
CHEST PAIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
FATIGUE			
subjects affected / exposed	3 / 8 (37.50%)	2 / 3 (66.67%)	
occurrences (all)	3	2	
EARLY SATIETY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CHILLS			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
MALAISE			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
INJECTION SITE EXTRAVASATION			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PAIN			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
OEDEMA PERIPHERAL			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
OEDEMA MUCOSAL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
OEDEMA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PYREXIA			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	
occurrences (all)	7	0	
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
ANISOMASTIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PROSTATIC DISORDER			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
ENDOMETRIAL THICKENING			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BREAST PAIN			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BREAST CYST			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
COUGH			
subjects affected / exposed	4 / 8 (50.00%)	1 / 3 (33.33%)	
occurrences (all)	7	1	
DRY THROAT			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ATELECTASIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HAEMOPTYSIS			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
EPISTAXIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
DYSPNOEA			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	2	
HICCUPS			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
NASAL CONGESTION				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
LARYNGEAL INFLAMMATION				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
HYPOXIA				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
OROPHARYNGEAL PAIN				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
PRODUCTIVE COUGH				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	2	0		
PULMONARY CONGESTION				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
PULMONARY MASS				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
UPPER RESPIRATORY TRACT INFLAMMATION				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
THROAT IRRITATION				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
RHINORRHOEA				
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)		
occurrences (all)	2	0		
SINUS CONGESTION				
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)		
occurrences (all)	1	1		

SINUS PAIN			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
RHINITIS ALLERGIC			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
WHEEZING			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	2	
AGITATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HALLUCINATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
DEPRESSION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CONFUSIONAL STATE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
LIBIDO DECREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	2	
AMYLASE INCREASED			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BLOOD CALCIUM DECREASED			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BLOOD CALCIUM INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BLOOD FIBRINOGEN DECREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BLOOD IMMUNOGLOBULIN G DECREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BLOOD LACTATE DEHYDROGENASE INCREASED			

subjects affected / exposed	1 / 8 (12.50%)	2 / 3 (66.67%)		
occurrences (all)	1	2		
BLOOD PHOSPHORUS DECREASED				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
BLOOD THYROID STIMULATING HORMONE INCREASED				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
EJECTION FRACTION DECREASED				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
GAMMA-GLUTAMYLTRANSFERASE INCREASED				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
INFLUENZA A VIRUS TEST POSITIVE				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
PROTEIN TOTAL DECREASED				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
OCCULT BLOOD POSITIVE				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
WEIGHT DECREASED				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
URINARY CASTS PRESENT				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
RED BLOOD CELLS URINE POSITIVE				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
PROTEIN URINE PRESENT				

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
LIPASE INCREASED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
INCISIONAL HERNIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
FALL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HAND FRACTURE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HIP FRACTURE			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ARTHROPOD BITE			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
RIB FRACTURE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PERIORBITAL HAEMATOMA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
LIGAMENT SPRAIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
INFUSION RELATED REACTION			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
SKIN LACERATION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
VASCULAR ACCESS SITE PAIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
TOOTH FRACTURE			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
SUNBURN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
SKIN WOUND			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
TACHYCARDIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
SINUS BRADYCARDIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
PALPITATIONS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
CORONARY ARTERY OCCLUSION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	

Nervous system disorders			
HEADACHE			
subjects affected / exposed	2 / 8 (25.00%)	1 / 3 (33.33%)	
occurrences (all)	5	1	
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
DIZZINESS			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
DYSGEUSIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
APHASIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
MIGRAINE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
LETHARGY			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
HYPOAESTHESIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
NEURALGIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PARAESTHESIA			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
RESTING TREMOR			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
SCIATICA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
SOMNOLENCE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
TASTE DISORDER			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
TREMOR			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
PANCYTOPENIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
NEUTROPENIA			
subjects affected / exposed	5 / 8 (62.50%)	1 / 3 (33.33%)	
occurrences (all)	23	3	
LYMPHADENOPATHY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPERGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
THROMBOCYTOPENIA			
subjects affected / exposed	4 / 8 (50.00%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
LEUKOPENIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
OTORRHOEA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
EAR PAIN			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
DEAFNESS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
DIPLOPIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
VISION BLURRED			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
SCLERAL HYPERAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PHOTOPHOBIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
LACRIMATION INCREASED			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
EYE PAIN			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
DRY MOUTH			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
DIARRHOEA			
subjects affected / exposed	6 / 8 (75.00%)	2 / 3 (66.67%)	
occurrences (all)	14	2	
DENTAL CARIES			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
CONSTIPATION			
subjects affected / exposed	4 / 8 (50.00%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	

ABDOMINAL DISTENSION				
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)		
occurrences (all)	0	1		
DYSPEPSIA				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
ABDOMINAL DISCOMFORT				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	2	0		
GASTROINTESTINAL DISORDER				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
FLATULENCE				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
DYSPHAGIA				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
FAECES DISCOLOURED				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
FAECES SOFT				
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)		
occurrences (all)	0	1		
GASTROINTESTINAL PAIN				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
GASTROOESOPHAGEAL REFLUX DISEASE				
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)		
occurrences (all)	2	0		
HAEMORRHOIDS				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
ORAL DISCHARGE				

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
ODYNOPHAGIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
NAUSEA			
subjects affected / exposed	4 / 8 (50.00%)	1 / 3 (33.33%)	
occurrences (all)	6	1	
MUCOUS STOOLS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
MOUTH ULCERATION			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
ORAL PAIN			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
VOMITING			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
TOOTHACHE			
subjects affected / exposed	2 / 8 (25.00%)	1 / 3 (33.33%)	
occurrences (all)	3	1	
STOMATITIS			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
HEPATIC STEATOSIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	

CHOLELITHIASIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
ACTINIC KERATOSIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
ALOPECIA			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
COLD SWEAT			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
DRY SKIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
ECCHYMOSIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ECZEMA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
HYPERHIDROSIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ERYTHEMA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
HYPERKERATOSIS			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
INGROWING NAIL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
MILIARIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
NIGHT SWEATS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
ONYCHOMADESIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
PRURITUS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
RASH ERYTHEMATOUS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
RASH			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
SKIN HYPERTROPHY			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
SKIN LESION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
SKIN ULCER			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
SOLAR LENTIGO			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			

POLLAKIURIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HAEMATURIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
DYSURIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
RENAL IMPAIRMENT			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
URINE ABNORMALITY			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
URINARY TRACT PAIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
URINARY INCONTINENCE			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ARTHRITIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
ARTHRALGIA			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
BONE PAIN			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
FLANK PAIN			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
MUSCULOSKELETAL DISCOMFORT			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
MUSCLE SPASMS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
JOINT STIFFNESS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
GROIN PAIN			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
MYALGIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PAIN IN JAW			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PLANTAR FASCIITIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PAIN IN EXTREMITY			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	5	0	
OSTEOPENIA			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
OSTEOARTHRITIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
CANDIDA INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CAMPYLOBACTER INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
BRONCHITIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
BACTERIAL DISEASE CARRIER			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
CHRONIC SINUSITIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CONJUNCTIVITIS			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
EAR INFECTION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

FUNGAL SKIN INFECTION				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
GASTROENTERITIS				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
GASTROINTESTINAL VIRAL INFECTION				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
OTITIS MEDIA				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
LOWER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	4	0		
NASOPHARYNGITIS				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
ORAL CANDIDIASIS				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
HERPES ZOSTER				
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
RESPIRATORY TRACT INFECTION				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
RHINITIS				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
RHINOVIRUS INFECTION				
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)		
occurrences (all)	0	1		
SINUSITIS				

subjects affected / exposed	4 / 8 (50.00%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
SKIN INFECTION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
TOOTH INFECTION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
PNEUMONIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
URINARY TRACT INFECTION ENTEROCOCCAL			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
DEHYDRATION			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPOALBUMINAEMIA			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPERURICAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPOCALCAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	2	1	
HYPERCALCAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
GOUT			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPERKALAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
HYPONATRAEMIA			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
HYPOKALAEMIA			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
TUMOUR LYSIS SYNDROME			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
VITAMIN D DEFICIENCY			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 August 2015	1. Inadvertent wording corrected regarding drug name: lenalidomide replaced with venetoclax. 2. Corrected schedule of imaging assessments for both relapsed/refractory FL and DLBCL patients so that the interim imaging scan should occur 7 days prior to C3D1.
01 August 2016	1. The amendment revised the DLT criteria, to include an additional cohort with a lower starting dose of venetoclax, and restart enrollment based on modified risk categorization for tumor lysis syndrome (TLS). 2. Added Cohort 1a with starting doses of 200 mg venetoclax and 1.4 mg/kg polatuzumab vedotin to collect safety data for this combination with obinutuzumab in response to observed adverse events. Cohort 1 will be repeated with the dose levels of 400 mg venetoclax and 1.4 mg/kg polatuzumab vedotin. 3. Enrollment rules into the dose escalation phase have been updated for participants' safety considerations. A sequential enrollment instead of a parallel enrolment will be used for each of the two dosing groups. 4. Added exclusion of participants with Grade 3b FL and a history of transformation of indolent disease to DLBCL in order to focus on a more homogenous patient population. 5. Clarified that CR at EOI on the basis of CT alone is to be determined by the IRC in addition to the investigator 6. Clarified the Modified Lugano Criteria for designation of PET-CT on the basis of PR to also include requirement of a CR or PR on CT-based response criteria. 7. Clarified pharmacokinetic and immunogenicity sampling schedule time windows.
17 January 2017	1. Protocol was updated to clarify that participants with R/R DLBCL were to receive polatuzumab vedotin and venetoclax in 2. The study design was updated to include a dose-escalation phase in R/R DLBCL participants to assess the maximum tolerated dose of venetoclax when combined with rituximab and polatuzumab at the 1.8 mg/kg dose level. Only venetoclax dosing will be escalated. combination with rituximab instead of obinutuzumab. 3. The defined primary populations to be analyzed was changed to include participants who received at least one dose of any component of the combination. 4. The immunogenicity analysis was updated to clarify that human anti-human antibodies will be collected for patients receiving obinutuzumab. 5. The interim analysis was clarified to state that enrollment would not be stopped in the case of higher than expected efficacy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported