Clinical trial results:
A Phase Ib/II, Open-Label Study Evaluating the Safety and Pharmacokinetics of GDC-0199 (ABT-199) in Combination With Rituximab (R) or Obinutuzumab (G) Plus Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Patients With B-Cell Non-Hodgkin's Lymphoma (NHL) and Diffuse Large B-cell Lymphoma (DLBCL)

Summary

EudraCT number	2013-003749-40
Trial protocol	FR NL HU CZ ES AT
Global end of trial date	

Results information

Result version number	v2
This version publication date	05 May 2019
First version publication date	12 July 2018
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	GO27878

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02055820
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hoffmann-La Roche
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	Medical Communications, Hoffmann-La Roche, +41 616878333, global.trial_information@roche.com
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	Interim
Date of interim/final analysis	28 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 June 2017
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

This is a multicenter, open-label, dose-finding study of venetoclax administered orally in combination with rituximab (R) or obinutuzumab (G) and standard doses of cyclophosphamide, doxorubicin, vincristine and oral prednisone (CHOP) in participants with Non-Hodgkin's Lymphoma (NHL). The study will consist of 2 stages: a dose-finding Phase Ib stage and a Phase II expansion stage. In the Phase I portion of the study, participants will be randomized to one of 2 treatment arms venetoclax in combination with R-CHOP (Arm A) and venetoclax in combination with G-CHOP (Arm B) and will explore the doses of venetoclax in combination with R-CHOP and G-CHOP. For the Phase II portion of the study, the venetoclax dose for venetoclax + R-CHOP is on a non-continuous dosing schedule as determined by the Phase Ib portion of the study based on safety and tolerability observed in participants treated in the dose escalation portion of the study.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 November 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 18
Country: Number of subjects enrolled	Austria: 11
Country: Number of subjects enrolled	Canada: 19
Country: Number of subjects enrolled	Czech Republic: 25
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	France: 63
Country: Number of subjects enrolled	Hungary: 12
Country: Number of subjects enrolled	Italy: 20
Country: Number of subjects enrolled	Netherlands: 8

Country: Number of subjects enrolled	United States: 77
Worldwide total number of subjects	264
EEA total number of subjects	150

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)	137
From 65 to 84 years	126
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The data reported for participant flow is based on safety population, which includes all participants who received at least one dose of study medication. There were 53 sites involved in 10 countries.

Pre-assignment

Screening details:

Phase I: Patients must have histologically confirmed Bcell NHL (never received RCHOP treatment), except MCL or SLL. Any relapsed/refractory patients should have received only a single previous treatment regimen Phase II: Patients must have previously untreated CD20positive DLBCL and IPI score must be 2-5.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Venetoclax + R-CHOP Arm

Arm description:

Phase I: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle will consist of 21 days. Phase II: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle will consist of 21 days. For both phase I and II, participants with ongoing response without excessive toxicity may receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Arm type	Experimental
Investigational medicinal product name	Venetoclax
Investigational medicinal product code	
Other name	GDC-0199
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Venetoclax 200 to 800 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I and MTD will be administered according to the same schedule during Phase II.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab 375 mg/m^2 dose administered IV on Day 1 of every 21-day cycle.

Arm title	Venetoclax + G-CHOP Arm

Arm description:

Phase I: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle will consist of 21 days. Phase II: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle will consist of 21 days. For both phase I and II, participants with ongoing response without excessive toxicity may receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Arm type	Experimental
Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Obinutuzumab administered by IV infusion as an absolute dose of 1000 mg on Days 1, 8, 15 of Cycle 1 and Day 1 of Cycles 2-8 (cycle length = 21 days).

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	
Other name	GDC-0199
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Venetoclax 200 to 800 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I and MTD will be administered according to the same schedule during Phase II.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

Number of subjects in period 1	Venetoclax + R-CHOP Arm	Venetoclax + G-CHOP Arm
Started	232	32
Completed	0	0
Not completed	232	32
Adverse event, serious fatal	19	-
Participants still in study	200	31
Consent withdrawn by subject	10	1
Lost to follow-up	3	-

Baseline characteristics

Reporting groups	
Reporting group title	Venetoclax + R-CHOP Arm
Reporting group description:	
Phase I: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle will consist of 21 days. Phase II: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle will consist of 21 days. For both phase I and II, participants with ongoing response without excessive toxicity may receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.	
Reporting group title	Venetoclax + G-CHOP Arm
Reporting group description:	
Phase I: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle will consist of 21 days. Phase II: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle will consist of 21 days. For both phase I and II, participants with ongoing response without excessive toxicity may receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.	

Reporting group values	Venetoclax + R-CHOP Arm	Venetoclax + G-CHOP Arm	Total
Number of subjects	232	32	264
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous Units: Years			
arithmetic mean	61.3	61.1	
standard deviation	± 12.6	± 11.4	-
Sex: Female, Male Units: Subjects			
Female	103	17	120
Male	129	15	144

End points

End points reporting groups

Reporting group title	Venetoclax + R-CHOP Arm

Reporting group description:

Phase I: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle will consist of 21 days. Phase II: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle will consist of 21 days. For both phase I and II, participants with ongoing response without excessive toxicity may receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax + G-CHOP Arm

Reporting group description:

Phase I: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle will consist of 21 days. Phase II: Participants will receive 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle will consist of 21 days. For both phase I and II, participants with ongoing response without excessive toxicity may receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 200 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 400 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 600 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 800 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 200 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 400 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical

Monitor.

Subject analysis set title	Venetoclax + G-CHOP 600 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 800 mg Phase II
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + Rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 800 mg Phase II
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + Rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 100 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 200 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 400 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 800 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 800 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 200 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 400 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 600 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 800 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 400 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 600 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants in the study. Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants in the study. Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants in the study. Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants in the study. Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants in the study. Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants in the study. Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants in the study. Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 800 mg Phase II
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + Rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 800 mg A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 800 mg A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + G-CHOP 800 mg B

Subject analysis set type	Sub-group analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Subject analysis set title	Venetoclax + R-CHOP 800mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

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

End point title	Safety: Number of Participants With Dose-Limiting Toxicities (DLTs)[1]

End point description:

DLTs were reported according to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 4.0 (NCI CTCAE v4.0). Decrease in B cells, lymphopenia, and leukopenia caused by lymphopenia were not considered DLTs but instead were expected outcomes of study treatment. Any Grade >/= 3 adverse event, that was attributed to having a reasonable possibility of being related to the combined administration of venetoclax plus R-CHOP or G-CHOP, that could not be attributed by the investigator to an alternative, clearly identifiable cause such as tumor progression, concurrent illness or medical condition, or concomitant medication and that occurred during the DLT observation period (start of venetoclax treatment through end of Cycle 2) was considered a DLT for dose-escalation purposes. Grade 3 or 4 neutropenia or thrombocytopenia identified on Day 1 of Cycle 2 or 3, resulting in dose delay were considered DLTs.

End point type	Primary

End point timeframe:

Start of venetoclax administration (Cycle 1 Day 4 or 3 days after first CHOP dose) up to end of Cycle 2 (cycle length = 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: Descriptive statistics only

End point values	Venetoclax + R-CHOP 200 mg	Venetoclax + R-CHOP 400 mg	Venetoclax + R-CHOP 600 mg	Venetoclax + G-CHOP 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	8	7
Units: Participants	1	0	1	2

End point values	Venetoclax + G-CHOP 400 mg	Venetoclax + G-CHOP 600 mg	Venetoclax + G-CHOP 800 mg A	Venetoclax + G-CHOP 800 mg B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	6	6
Units: Participants	1	1	0	0

End point values	Venetoclax + R-CHOP 800mg			

Subject group type	Subject analysis set			
Number of subjects analysed	6			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET-CT) Scan Using the Modified Lugano Classification assessed by Independent Review Committee (IRC)

End point title	Percentage of Participants With Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET-CT) Scan Using the Modified Lugano Classification assessed by Independent Review Committee (IRC)[2]

End point description:

CR was defined as follows according to modified Lugano classification for PET-CT-based response: Lymph nodes and extra-lymphatic sites with score 1, 2, or 3 with or without a residual mass on 5-point scale with 1) no uptake above background; 2) uptake </= mediastinum; 3) uptake < mediastinum but </= liver. No evidence of fluorodeoxyglucose (FDG)-uptake disease in marrow. If the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. Intent-to-treat. All participants who enrolled in the study were included in the ITT population.

End point type	Primary

End point timeframe:

Baseline up to end of treatment (up to approximately 36 months)

Notes:

[2] - 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: Descriptive statistics only

End point values	Venetoclax + R-CHOP 800 mg Phase II			
Subject group type	Subject analysis set			
Number of subjects analysed	211[3]			
Units: Percentage of participants				
number (confidence interval 95%)	68.2 (61.50 to 74.47)			

Notes:

[3] - All participants who enrolled in the study were included in the ITT population

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With CR Defined by PET/CT Scan in Dual Expressor Diffuse Large B-Cell Lymphoma (DE-DLBCL) Participants assessed by IRC

End point title	Percentage of Participants With CR Defined by PET/CT Scan in Dual Expressor Diffuse Large B-Cell Lymphoma (DE-DLBCL) Participants assessed by IRC[4]

End point description:

CR was defined as follows according to modified Lugano classification for PET/CT-based response: Lymph nodes and extra-lymphatic sites with score 1, 2, or 3 with or without a residual mass on 5-point

scale with 1) no uptake above background; 2) uptake </= mediastinum; 3) uptake < mediastinum but </= liver. No evidence of fluorodeoxyglucose (FDG)-uptake disease in marrow. If the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Primary

End point timeframe:

Baseline up to end of treatment (up to approximately 36 months)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics only

End point values	Venetoclax + R-CHOP 800 mg Phase II			
Subject group type	Subject analysis set			
Number of subjects analysed	81[5]			
Units: Percentage of participants				
number (confidence interval 95%)	66.7 (55.32 to 76.76)			

Notes:

[5] - All participants who enrolled in the study were included in the ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Venetoclax Plasma PK: Area Under the Plasma Concentration-Time Curve (AUC)

End point title	Venetoclax Plasma PK: Area Under the Plasma Concentration-Time Curve (AUC)

End point description:

AUC was calculated based on measurement of venetoclax concentration in plasma over time. Data are reported as hour*micrograms per milliliter (hr*mcg/mL). PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample. 99999=N/A

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 hours (Hr) postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

End point values	Venetoclax + R-CHOP 600 mg	Venetoclax + G-CHOP 200 mg	Venetoclax + G-CHOP 400 mg	Venetoclax + G-CHOP 600 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	7	7	6
Units: hr*mcg/mL				
arithmetic mean (standard deviation)	3.70 (± 1.59)	2.55 (± 1.13)	4.33 (± 1.31)	5.13 (± 2.41)

End point values	Venetoclax + R-CHOP 100 mg	Venetoclax + R-CHOP 200 mg	Venetoclax + R-CHOP 400 mg	Venetoclax + G-CHOP 800 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	6	4	10
Units: hr*mcg/mL				
arithmetic mean (standard deviation)	.66 (± 99999)	2.51 (± .97)	3.87 (± 2.41)	6.20 (± 1.71)

End point values	Venetoclax + R-CHOP 800 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: hr*mcg/mL				
arithmetic mean (standard deviation)	4.51 (± 2.32)			

Statistical analyses

No statistical analyses for this end point

Secondary: Venetoclax Plasma PK: Time to Maximum Observed Plasma Concentration (Tmax)

End point title	Venetoclax Plasma PK: Time to Maximum Observed Plasma Concentration (Tmax)

End point description:

Tmax was determined based on measurement of venetoclax concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample. 99999=N/A

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 Hr postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

End point values	Venetoclax + R-CHOP 600 mg	Venetoclax + G-CHOP 200 mg	Venetoclax + G-CHOP 400 mg	Venetoclax + G-CHOP 600 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	7	7	6
Units: Hour				
arithmetic mean (standard deviation)	5.52 (± 2.07)	5.72 (± 1.42)	6.56 (± 1.51)	5.30 (± 2.38)

End point values	Venetoclax + R-CHOP 100 mg	Venetoclax + R-CHOP 200 mg	Venetoclax + R-CHOP 400 mg	Venetoclax + G-CHOP 800 mg

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	6	4	10
Units: Hour				
arithmetic mean (standard deviation)	4.0 (± 99999)	4.59 (± 1.08)	6.50 (± 1.91)	5.79 (± 1.47)

End point values	Venetoclax + R-CHOP 800 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: Hour				
arithmetic mean (standard deviation)	5.53 (± 1.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Venetoclax Plasma PK: Maximum Observed Plasma Concentration (Cmax)

End point title	Venetoclax Plasma PK: Maximum Observed Plasma Concentration (Cmax)

End point description:

Cmax was determined based on measurement of venetoclax concentrations in plasma over time. Data are reported as micrograms per milliliter. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample. 99999=N/A

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 Hr postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

End point values	Venetoclax + R-CHOP 600 mg	Venetoclax + G-CHOP 200 mg	Venetoclax + G-CHOP 400 mg	Venetoclax + G-CHOP 600 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	7	7	6
Units: Ug/ML				
arithmetic mean (standard deviation)	.85 (± .33)	.52 (± .21)	1.26 (± .30)	1.00 (± .58)

End point values	Venetoclax + R-CHOP 100 mg	Venetoclax + R-CHOP 200 mg	Venetoclax + R-CHOP 400 mg	Venetoclax + G-CHOP 800 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	6	4	10
Units: Ug/ML				

arithmetic mean (standard deviation)	.09 (± 99999)	.58 (± .32)	.92 (± .64)	1.54 (± .37)

End point values	Venetoclax + R-CHOP 800 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: Ug/ML				
arithmetic mean (standard deviation)	1.15 (± .48)			

Statistical analyses

No statistical analyses for this end point

Secondary: Venetoclax Plasma PK: Minimum Plasma Concentration (Cmin) within the Dosing Interval

End point title	Venetoclax Plasma PK: Minimum Plasma Concentration (Cmin) within the Dosing Interval

End point description:

Cmin was determined based on measurement of venetoclax concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 Hr postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

End point values	Venetoclax + G-CHOP 800 mg	Venetoclax + G-CHOP 200 mg	Venetoclax + R-CHOP 100 mg	Venetoclax + R-CHOP 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	7	1	3
Units: mcg/mL				
arithmetic mean (standard deviation)	0.628 (± 0.395)	0.134 (± 0.107)	0.0714 (± 0.00)	0.522 (± 0.441)

End point values	Venetoclax + R-CHOP 400 mg	Venetoclax + R-CHOP 600 mg	Venetoclax + R-CHOP 800 mg	Venetoclax + G-CHOP 400 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	4	126	5
Units: mcg/mL				
arithmetic mean (standard deviation)	0.253 (± 0.247)	0.387 (± 0.141)	0.640 (± 0.451)	0.395 (± 0.381)

End point values	Venetoclax + G-CHOP 600 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: mcg/mL				
arithmetic mean (standard deviation)	0.612 (± 0.535)			

Statistical analyses

No statistical analyses for this end point

Secondary: Prednisone Plasma PK: AUC

End point title	Prednisone Plasma PK: AUC

End point description:

AUC was determined based on measurement of Predisone concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) and 0.5, 1, 2, 4, 6 Hr after prednisone dose on Day 1 of Cycle 1 and 2 (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: hr*mcg/mL				
arithmetic mean (standard deviation)				
Cycle 1, Day 1|	195 (± 72.8)			
Cycle 2, Day 1|	184 (± 81.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Prednisone Plasma PK: Tmax

End point title	Prednisone Plasma PK: Tmax

End point description:

Tmax was determined based on measurement of Predisone concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) and 0.5, 1, 2, 4, 6 Hr after prednisone dose on Day 1 of Cycle 1 and 2 (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: Hour				
arithmetic mean (standard deviation)				
Cycle 1, Day 1|	2.19 (± 1.61)			
Cycle 2, Day 1|	3.80 (± 2.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Prednisone Plasma PK: Cmax

End point title	Prednisone Plasma PK: Cmax

End point description:

Cmax was determined based on measurement of Predisone concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) and 0.5, 1, 2, 4, 6 Hr after prednisone dose on Day 1 of Cycle 1 and 2 (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: Ng/ML				
arithmetic mean (standard deviation)				
Cycle 1, Day 1|	49.9 (± 28.7)			
Cycle 2, Day 1|	43.2 (± 17.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rituximab PK: Cmax

End point title	Rituximab PK: Cmax

End point description:

Cmax was determined based on measurement of Rituximab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) on Day 1 of Cycles 1-8; end of infusion (infusion duration = 2-3 hours) on Cycle 1 Day 1; anytime during end of treatment (6-9 weeks after Cycle 8 Day 1) (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: mcg/mL				
arithmetic mean (standard deviation)	173 (± 39.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rituximab PK: Cmin within the Dosing Interval

End point title	Rituximab PK: Cmin within the Dosing Interval

End point description:

Cmin was determined based on measurement of Rituximab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) on Day 1 of Cycles 1-8; end of infusion (infusion duration = 2-3 hours) on Cycle 1 Day 1 (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: mcg/mL				
arithmetic mean (standard deviation)	26.1 (± 13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Obinutuzumab PK: Cmax

End point title	Obinutuzumab PK: Cmax

End point description:

Cmax was determined based on measurement of Obinutuzumab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) on Day 1 of Cycles 1-8; predose (within 30 minutes) and end of infusion (infusion duration = 3 Hr) on Day 1 of Cycles 1 and 2; anytime during end of treatment (6-9 weeks after Cycle 8 Day 1) (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: mcg/mL				
arithmetic mean (standard deviation)	326 (± 76)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cyclophosphamide PK: Cmax

End point title	Cyclophosphamide PK: Cmax

End point description:

Cmax was determined based on measurement of Cyclophosphamide concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) and end of infusion (infusion duration = 30 minutes) on Day 1 of Cycles 1 and 2 (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	36			
Units: mcg/mL				
arithmetic mean (standard deviation)	32.1 (± 7.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doxorubicin PK: Cmax

End point title	Doxorubicin PK: Cmax

End point description:

Cmax was determined based on measurement of Doxorubicin concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) and end of infusion (infusion duration = 15-30 minutes) on Day 1 of Cycles 1 and 2 (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	24			
Units: mcg/mL				
arithmetic mean (standard deviation)	1260 (± 911)			

Statistical analyses

No statistical analyses for this end point

Secondary: Vincristine PK: Cmax

End point title	Vincristine PK: Cmax

End point description:

Cmax was determined based on measurement of Rituximab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

End point type	Secondary

End point timeframe:

Predose (within 30 minutes) and end of infusion (infusion duration = 10 minutes) on Day 1 of Cycles 1 and 2 (cycle length = 21 days)

End point values	Venetoclax			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: mcg/mL				
arithmetic mean (standard deviation)	54.0 (± 44.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Objective Response Defined as Partial Response (PR) or Complete Response (CR) Using the Modified Lugano Classification

End point title	Percentage of Participants With Objective Response Defined as Partial Response (PR) or Complete Response (CR) Using the Modified Lugano Classification

End point description:

Objective Response defined as PR (partial response) or CR (complete response) at end of treatment. CR: Lymph nodes and extra-lymphatic sites with score 1, 2 or 3 on a 5-point scale (with a higher score being a worse outcome). No evidence of fluorodeoxyglucose (FDG)-uptake disease in marrow. If the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. PR: Lymph nodes and extralymphatic sites with score of 4 or 5 on the 5-point scale with reduced uptake compared with baseline and residual mass(es) of any size. CT-based response criteria for PR must also be met. No new lesions. In bone marrow residual uptake could be higher than in normal marrow but must be reduced compared with baseline; persistent focal changes in the marrow to be considered for further evaluation with magnetic resonance imaging (MRI) or biopsy or an interval scan. OR=PR+CR

End point type	Secondary

End point timeframe:

Baseline up to disease progression or death due to any cause, whichever occurs first (up to approximately 36 months)

End point values	Venetoclax + R-CHOP 800 mg Phase II			
Subject group type	Subject analysis set			
Number of subjects analysed	211[6]			
Units: Percentage of Participants				
number (confidence interval 95%)	81.5 (75.61 to 86.51)			

Notes:

[6] - All participants who enrolled in the study were included in the ITT population.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who are Alive and Without Disease Progression at Month 12

End point title	Percentage of Participants who are Alive and Without Disease Progression at Month 12

End point description:

Progressive disease (PD) was determined using the modified Lugano classification criteria. For PET-CT-based PD: Score 4 (uptake moderately > liver) or 5 (uptake markedly higher than liver and/or new lesions) with an increase in intensity of uptake from baseline in target nodes and nodal lesions, new FDG-uptake foci of extranodal lesions consistent with lymphoma at interim or end-of-treatment assessment, no non-measured lesions, new FDG-uptake foci consistent with lymphoma, new or recurrent FDG-uptake foci in bone marrow. For CT-based PD: >/= 50% decrease in SPD of up to 6 target measureable nodes and extranodal sites; non-measured lesion should be absent/normal, have regressed, but not increased; no new lesions. All participants who enrolled in the study were included in the ITT population

End point type	Secondary

End point timeframe:

Month 12

End point values	Venetoclax + R-CHOP 200 mg	Venetoclax + R-CHOP 400 mg	Venetoclax + R-CHOP 600 mg	Venetoclax + G-CHOP 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	8	7
Units: Percentage of Participants				
number (confidence interval 95%)	85.71 (59.79 to 100.00)	100.00 (100.00 to 100.00)	87.50 (64.58 to 100.00)	100.00 (100.00 to 100.00)

End point values	Venetoclax + G-CHOP 400 mg	Venetoclax + G-CHOP 600 mg	Venetoclax + R-CHOP 800 mg Phase II	Venetoclax + G-CHOP 800 mg A
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	211	6
Units: Percentage of Participants				
number (confidence interval 95%)	75.00 (32.57 to 100.00)	100.00 (100.00 to 100.00)	83.62 (76.97 to 90.27)	100.00 (100.00 to 100.00)

End point values	Venetoclax + G-CHOP 800 mg B	Venetoclax + R-CHOP 800mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	4		
Units: Percentage of Participants				
number (confidence interval 95%)	100.00 (100.00 to 100.00)	66.67 (28.95 to 100.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With CR Defined by Computed Tomography (CT) Scan Using the Modified Lugano Classification

End point title	Percentage of Participants With CR Defined by Computed Tomography (CT) Scan Using the Modified Lugano Classification

End point description:

CR was defined as follows according to modified Lugano classification for CT-based response: Target nodes/nodal masses must have regressed to </= 1.5 cm in longest transverse diameter of a lesion (LDi), no extra-lymphatic sites of disease, absence of non-measured lesions, organ enlargement must have regressed to normal, no new lesions, and if the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. All participants who enrolled in the study were included in the ITT population

End point type	Secondary

End point timeframe:

Baseline up to disease progression or death due to any cause, whichever occurs first (up to approximately 36 months)

End point values	Venetoclax + R-CHOP 800 mg Phase II			
Subject group type	Subject analysis set			
Number of subjects analysed	211			
Units: Percentage of Participants				
number (confidence interval 95%)	37.4 (30.89 to 44.35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Safety: Percentage of Participants With Adverse Events

End point title	Safety: Percentage of Participants With Adverse Events

End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events. All patients who enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP were included in the safety population.

End point type	Secondary

End point timeframe:

Baseline up to approximately 36 months

End point values	Venetoclax + R-CHOP 200 mg	Venetoclax + R-CHOP 400 mg	Venetoclax + R-CHOP 600 mg	Venetoclax + G-CHOP 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	8	7
Units: Percentage of Participants				
number (not applicable)	100.00	100.00	100.00	100.00

End point values	Venetoclax + G-CHOP 400 mg	Venetoclax + G-CHOP 600 mg	Venetoclax + R-CHOP 800 mg Phase II	Venetoclax + G-CHOP 800 mg A
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	208	6
Units: Percentage of Participants				

number (not applicable)	100.00	100.00	98.6	100.0

End point values	Venetoclax + G-CHOP 800 mg B	Venetoclax + R-CHOP 800mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	6		
Units: Percentage of Participants				
number (not applicable)	100.00	100.00		

Statistical analyses

No statistical analyses for this end point

Secondary: Safety: Percentage of Participants Maintaining Relative Dose Intensity of CHOP Chemotherapy

End point title	Safety: Percentage of Participants Maintaining Relative Dose Intensity of CHOP Chemotherapy

End point description:

Maintenance of relative dose intensity was defined as a dose intensity of >/= 90%. All patients who enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP were included in the safety population.

End point type	Secondary

End point timeframe:

Baseline up to Cycle 6 (cycle length = 21 days)

End point values	Venetoclax + R-CHOP Arm	Venetoclax + G-CHOP Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	232	32		
Units: Percentage of participants				
number (not applicable)				
Cyclophosphamide|	89.5	77.4		
Doxorubicin|	88.6	77.4		
Vincristine|	86.6	78.1		
Prednisone|	87.4	81.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Relative Dose Intensity of Venetoclax

End point title	Relative Dose Intensity of Venetoclax

End point description:

Dose intensity was categorized as < 80%, 80% to < 85%, 85% to < 90%, or >/= 90%. All patients who enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP were included in the safety population

End point type	Secondary

End point timeframe:

Baseline up to Cycle 6 (cycle length = 21 days)

End point values	Venetoclax + R-CHOP 200 mg	Venetoclax + R-CHOP 400 mg	Venetoclax + R-CHOP 600 mg	Venetoclax + G-CHOP 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	8	7
Units: Percentage of Partcipants				
number (not applicable)				
<80%|	71.4	0.00	12.5	100.00
80-<85%|	0.00	0.00	12.5	0.00
85-<90%|	0.00	0.00	12.5	0.00
>=90%|	28.6	100.00	62.5	0.00

End point values	Venetoclax + G-CHOP 400 mg	Venetoclax + G-CHOP 600 mg	Venetoclax + R-CHOP 800 mg Phase II	Venetoclax + G-CHOP 800 mg A
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	208	6
Units: Percentage of Partcipants				
number (not applicable)				
<80%|	14.3	50.0	26.0	83.3
80-<85%|	14.3	16.7	3.4	0.00
85-<90%|	0.00	0.00	2.9	16.7
>=90%|	71.4	33.3	67.6	0.00

End point values	Venetoclax + G-CHOP 800 mg B	Venetoclax + R-CHOP 800mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	6		
Units: Percentage of Partcipants				
number (not applicable)				
<80%|	100.00	0.00		
80-<85%|	0.00	0.00		
85-<90%|	0.00	0.00		
>=90%|	0.00	0.00		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to approximately 50 months

Adverse event reporting additional description:

Safety population: All participants, who were enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP, were included in the safety population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Venetoclax+R-CHOP 200 mg

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+R-CHOP 400 mg

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+R-CHOP 600 mg

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+R-CHOP 800 mg

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+R-CHOP 800 mg Phase II

Reporting group description:

Phase II: Participants received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+G-CHOP 200 mg

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+G-CHOP 400 mg

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+G-CHOP 600 mg

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+G-CHOP 800 mg A

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Reporting group title	Venetoclax+G-CHOP 800 mg B

Reporting group description:

Phase I: Participants received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Participants who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

Serious adverse events	Venetoclax+R-CHOP 200 mg	Venetoclax+R-CHOP 400 mg	Venetoclax+R-CHOP 600 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	2 / 3 (66.67%)	3 / 8 (37.50%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Hypotension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (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
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Sudden cardiac death			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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

Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Lung disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Organising pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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
Psychotic disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Biopsy salivary gland			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 potassium increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
C−reactive protein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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

Spinal fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Toxicity to various agents			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 arrest			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Cardiogenic shock			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	1 / 3 (33.33%)	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
Myocardial ischaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Carotid sinus syndrome			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (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
Epilepsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Hypoglossal nerve paresis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Polyneuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Agranulocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	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
Febrile neutropenia			
subjects affected / exposed	3 / 7 (42.86%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	5 / 5	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (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
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Optic neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Diverticular perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Duodenal stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Dysphagia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Enterocolitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Gastric dilatation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Gastric perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Gastric stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Gastric ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Gastric ulcer perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Haematemesis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Ileal perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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
Obstruction gastric			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Oesophageal stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pancreatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Cholecystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Cholecystitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Drug−induced liver injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Skin and subcutaneous tissue disorders			

Rash maculo−papular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Joint swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Spondylolisthesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Atypical pneumonia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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 colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Device related infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (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
Diverticulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Escherichia pyelonephritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Gastroenteritis norovirus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Herpes simplex			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Lung infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Meningitis viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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 respiratory syncytial viral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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
Rhinovirus infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (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
Root canal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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 / 7 (0.00%)	0 / 3 (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 pseudomonal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Hyponatraemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Venetoclax+R-CHOP 800 mg	Venetoclax+R-CHOP 800 mg Phase II	Venetoclax+G-CHOP 200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	114 / 208 (54.81%)	5 / 7 (71.43%)
number of deaths (all causes)	2	15	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
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 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	6 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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

Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Lung disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Biopsy salivary gland			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C−reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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

Toxicity to various agents			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	6 / 208 (2.88%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Cardiogenic shock			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Cardiomyopathy			

subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Nervous system disorders			
Carotid sinus syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Hypoglossal nerve paresis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Polyneuropathy			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	2 / 6 (33.33%)	60 / 208 (28.85%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	3 / 3	90 / 94	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	17 / 208 (8.17%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	21 / 21	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Eye disorders			
Optic neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric dilatation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Gastric stenosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Gastric ulcer perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Haematemesis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Ileal perforation			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
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 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Obstruction gastric			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Oesophageal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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 / 6 (0.00%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Drug−induced liver injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash maculo−papular			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (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
Spondylolisthesis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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			
Acute sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Atypical pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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

Clostridium colitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Gastroenteritis norovirus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Infection			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	1 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (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
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Neutropenic infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Oral herpes			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	8 / 208 (3.85%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	6 / 8	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Pseudomonas infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Rhinovirus infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Root canal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	6 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Viral infection			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
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	Venetoclax+G-CHOP	Venetoclax+G-CHOP	Venetoclax+G-CHOP

	400 mg	600 mg	800 mg A
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)	3 / 6 (50.00%)	5 / 6 (83.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (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
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Organising pneumonia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (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
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Biopsy salivary gland			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood potassium increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C−reactive protein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid sinus syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglossal nerve paresis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Optic neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric dilatation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug−induced liver injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash maculo−papular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (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 respiratory syncytial viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Root canal infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Venetoclax+G-CHOP 800 mg B		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inflammation			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden cardiac death			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Organising pneumonia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pleural effusion				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Productive cough				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Confusional state				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychotic disorder				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Biopsy salivary gland				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood potassium increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

C−reactive protein increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Infusion related reaction				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament rupture				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post lumbar puncture syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute coronary syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Atrial fibrillation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomyopathy				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Carotid sinus syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglossal nerve paresis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polyneuropathy				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Haemolytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			

Optic neuropathy				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Diarrhoea				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticular perforation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal stenosis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric dilatation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric perforation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric stenosis				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer perforation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileal perforation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstruction gastric				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal stenosis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct stone				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug−induced liver injury				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Rash maculo−papular				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint swelling				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pain in extremity				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spondylolisthesis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Acute sinusitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atypical pneumonia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium colitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia pyelonephritis				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes simplex				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis viral				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Oral candidiasis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral herpes				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonas infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Root canal infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection pseudomonal				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased appetite				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus inadequate control				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour lysis syndrome			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Venetoclax+R-CHOP 200 mg	Venetoclax+R-CHOP 400 mg	Venetoclax+R-CHOP 600 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	3 / 3 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Squamous cell carcinoma			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Lung neoplasm malignant			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	3 / 8 (37.50%)
occurrences (all)	2	2	3
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 7 (71.43%)	0 / 3 (0.00%)	3 / 8 (37.50%)
occurrences (all)	5	0	3
Gait disturbance			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Non−cardiac chest pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	2
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Unevaluable event			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Testicular pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	3 / 8 (37.50%)
occurrences (all)	2	0	4
Dyspnoea			
subjects affected / exposed	3 / 7 (42.86%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	4	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Hiccups			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Rhinorrhoea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Sinus pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vocal cord dysfunction			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Mood swings			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Investigations			
Blood potassium increased			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Weight increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram thorax abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	1 / 7 (14.29%)	2 / 3 (66.67%)	1 / 8 (12.50%)
occurrences (all)	1	2	1
Muscle strain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tracheal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Ichthyosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cardiac failure			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Carotid sinus syndrome			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Cognitive disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	3
Memory impairment			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	3 / 8 (37.50%)
occurrences (all)	2	2	3
Paraesthesia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 7 (42.86%)	1 / 3 (33.33%)	2 / 8 (25.00%)
occurrences (all)	3	1	2
Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Syncope			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Ageusia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 7 (57.14%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	9	0	1
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haemolytic anaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	4 / 7 (57.14%)	2 / 3 (66.67%)	5 / 8 (62.50%)
occurrences (all)	9	8	15
Pancytopenia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	4 / 7 (57.14%)	1 / 3 (33.33%)	2 / 8 (25.00%)
occurrences (all)	7	2	4
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Vision blurred			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	2 / 3 (66.67%)	3 / 8 (37.50%)
occurrences (all)	1	2	3
Diarrhoea			
subjects affected / exposed	3 / 7 (42.86%)	2 / 3 (66.67%)	2 / 8 (25.00%)
occurrences (all)	10	4	2
Dyspepsia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Gingival pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Nausea			
subjects affected / exposed	3 / 7 (42.86%)	2 / 3 (66.67%)	1 / 8 (12.50%)
occurrences (all)	3	4	1
Oral pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Proctalgia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	2	1	1
Toothache			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dental cyst			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Nail discolouration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pigmentation disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Rash maculo−papular			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail disorder			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Urinary tract pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	4	0	0
Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Muscular weakness			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Campylobacter gastroenteritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia klebsiella			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pseudomonal bacteraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Device related infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis orbital			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0

Hypokalaemia			
subjects affected / exposed	3 / 7 (42.86%)	1 / 3 (33.33%)	2 / 8 (25.00%)
occurrences (all)	4	1	2
Hypomagnesaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	6	0	0
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tumour lysis syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Venetoclax+R-CHOP 800 mg	Venetoclax+R-CHOP 800 mg Phase II	Venetoclax+G-CHOP 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	205 / 208 (98.56%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Papillary thyroid cancer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lung neoplasm malignant			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	13 / 208 (6.25%)	1 / 7 (14.29%)
occurrences (all)	0	15	1
Thrombophlebitis			
subjects affected / exposed	1 / 6 (16.67%)	3 / 208 (1.44%)	1 / 7 (14.29%)
occurrences (all)	1	3	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	33 / 208 (15.87%)	2 / 7 (28.57%)
occurrences (all)	0	41	2
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	11 / 208 (5.29%)	0 / 7 (0.00%)
occurrences (all)	0	11	0
Chills			
subjects affected / exposed	1 / 6 (16.67%)	11 / 208 (5.29%)	0 / 7 (0.00%)
occurrences (all)	1	13	0
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)	80 / 208 (38.46%)	5 / 7 (71.43%)
occurrences (all)	4	113	7
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Malaise			

subjects affected / exposed	0 / 6 (0.00%)	6 / 208 (2.88%)	1 / 7 (14.29%)
occurrences (all)	0	6	2
Mucosal inflammation			
subjects affected / exposed	1 / 6 (16.67%)	20 / 208 (9.62%)	1 / 7 (14.29%)
occurrences (all)	1	32	1
Non−cardiac chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	24 / 208 (11.54%)	0 / 7 (0.00%)
occurrences (all)	0	29	0
Pyrexia			
subjects affected / exposed	2 / 6 (33.33%)	49 / 208 (23.56%)	0 / 7 (0.00%)
occurrences (all)	2	67	0
Unevaluable event			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Feeling abnormal			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	1 / 7 (14.29%)
occurrences (all)	0	5	1
Infusion site extravasation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	6 / 208 (2.88%)	1 / 7 (14.29%)
occurrences (all)	0	7	1
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vaginal discharge			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 6 (16.67%)	52 / 208 (25.00%)	3 / 7 (42.86%)
occurrences (all)	1	71	3
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	22 / 208 (10.58%)	0 / 7 (0.00%)
occurrences (all)	1	24	0
Dyspnoea exertional			
subjects affected / exposed	1 / 6 (16.67%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	1	4	0
Hiccups			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	5	0
Nasal congestion			
subjects affected / exposed	1 / 6 (16.67%)	11 / 208 (5.29%)	2 / 7 (28.57%)
occurrences (all)	1	11	2
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	13 / 208 (6.25%)	1 / 7 (14.29%)
occurrences (all)	0	13	1
Sinus pain			

subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vocal cord dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	7	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	10 / 208 (4.81%)	1 / 7 (14.29%)
occurrences (all)	0	13	1
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	9 / 208 (4.33%)	1 / 7 (14.29%)
occurrences (all)	1	9	3
Depression			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	5	0
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)	15 / 208 (7.21%)	2 / 7 (28.57%)
occurrences (all)	1	18	2
Mood swings			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Investigations			
Blood potassium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 6 (16.67%)	32 / 208 (15.38%)	0 / 7 (0.00%)
occurrences (all)	1	33	0
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood magnesium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram thorax abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Urine output decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Infusion related reaction			
subjects affected / exposed	2 / 6 (33.33%)	44 / 208 (21.15%)	4 / 7 (57.14%)
occurrences (all)	3	48	4
Muscle strain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tracheal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Ichthyosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	1 / 7 (14.29%)
occurrences (all)	0	8	1
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	8 / 208 (3.85%)	0 / 7 (0.00%)
occurrences (all)	0	8	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Cardiac failure			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Nervous system disorders			
Carotid sinus syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 6 (16.67%)	23 / 208 (11.06%)	1 / 7 (14.29%)
occurrences (all)	1	31	1
Dysgeusia			
subjects affected / exposed	1 / 6 (16.67%)	23 / 208 (11.06%)	1 / 7 (14.29%)
occurrences (all)	1	28	1
Headache			
subjects affected / exposed	1 / 6 (16.67%)	27 / 208 (12.98%)	3 / 7 (42.86%)
occurrences (all)	1	30	5
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Neuropathy peripheral			
subjects affected / exposed	3 / 6 (50.00%)	27 / 208 (12.98%)	0 / 7 (0.00%)
occurrences (all)	3	33	0
Paraesthesia			
subjects affected / exposed	1 / 6 (16.67%)	18 / 208 (8.65%)	0 / 7 (0.00%)
occurrences (all)	1	25	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 6 (33.33%)	14 / 208 (6.73%)	0 / 7 (0.00%)
occurrences (all)	2	14	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1

Syncope			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	8	0
Ageusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	1 / 7 (14.29%)
occurrences (all)	0	4	1
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 6 (33.33%)	72 / 208 (34.62%)	1 / 7 (14.29%)
occurrences (all)	3	116	1
Febrile neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	13 / 208 (6.25%)	0 / 7 (0.00%)
occurrences (all)	3	17	0
Haemolytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	24 / 208 (11.54%)	0 / 7 (0.00%)
occurrences (all)	0	48	0
Neutropenia			
subjects affected / exposed	2 / 6 (33.33%)	130 / 208 (62.50%)	2 / 7 (28.57%)
occurrences (all)	9	356	2
Pancytopenia			

subjects affected / exposed	1 / 6 (16.67%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	54 / 208 (25.96%)	2 / 7 (28.57%)
occurrences (all)	0	88	3
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	7	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	14 / 208 (6.73%)	0 / 7 (0.00%)
occurrences (all)	0	15	0
Abdominal pain			

subjects affected / exposed	1 / 6 (16.67%)	31 / 208 (14.90%)	0 / 7 (0.00%)
occurrences (all)	1	39	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	1 / 7 (14.29%)
occurrences (all)	0	13	1
Constipation			
subjects affected / exposed	2 / 6 (33.33%)	67 / 208 (32.21%)	6 / 7 (85.71%)
occurrences (all)	2	78	7
Diarrhoea			
subjects affected / exposed	3 / 6 (50.00%)	79 / 208 (37.98%)	5 / 7 (71.43%)
occurrences (all)	5	136	5
Dyspepsia			
subjects affected / exposed	1 / 6 (16.67%)	22 / 208 (10.58%)	1 / 7 (14.29%)
occurrences (all)	1	27	1
Dysphagia			
subjects affected / exposed	1 / 6 (16.67%)	7 / 208 (3.37%)	1 / 7 (14.29%)
occurrences (all)	1	9	1
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 6 (33.33%)	6 / 208 (2.88%)	0 / 7 (0.00%)
occurrences (all)	2	7	0
Gingival pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Haemorrhoids			
subjects affected / exposed	1 / 6 (16.67%)	15 / 208 (7.21%)	0 / 7 (0.00%)
occurrences (all)	1	17	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	6 / 208 (2.88%)	0 / 7 (0.00%)
occurrences (all)	0	6	0
Nausea			
subjects affected / exposed	5 / 6 (83.33%)	108 / 208 (51.92%)	3 / 7 (42.86%)
occurrences (all)	7	172	5
Oral pain			
subjects affected / exposed	1 / 6 (16.67%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Proctalgia			

subjects affected / exposed	1 / 6 (16.67%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Stomatitis			
subjects affected / exposed	2 / 6 (33.33%)	23 / 208 (11.06%)	0 / 7 (0.00%)
occurrences (all)	2	28	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)	63 / 208 (30.29%)	5 / 7 (71.43%)
occurrences (all)	6	110	5
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Dental caries			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dental cyst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences (all)	0	5	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Gastric ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	1 / 7 (14.29%)
occurrences (all)	0	5	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	3 / 6 (50.00%)	27 / 208 (12.98%)	0 / 7 (0.00%)
occurrences (all)	3	28	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	8 / 208 (3.85%)	0 / 7 (0.00%)
occurrences (all)	0	9	0
Hyperhidrosis			
subjects affected / exposed	1 / 6 (16.67%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Nail discolouration			
subjects affected / exposed	1 / 6 (16.67%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Pigmentation disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	6 / 208 (2.88%)	0 / 7 (0.00%)
occurrences (all)	0	8	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	9 / 208 (4.33%)	0 / 7 (0.00%)
occurrences (all)	0	9	0
Rash maculo−papular			
subjects affected / exposed	1 / 6 (16.67%)	6 / 208 (2.88%)	1 / 7 (14.29%)
occurrences (all)	1	6	1
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail disorder			

subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Bladder hypertrophy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	1 / 6 (16.67%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Urinary tract pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nocturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)	22 / 208 (10.58%)	1 / 7 (14.29%)
occurrences (all)	1	23	1
Bone pain			
subjects affected / exposed	1 / 6 (16.67%)	10 / 208 (4.81%)	2 / 7 (28.57%)
occurrences (all)	1	11	2
Back pain			
subjects affected / exposed	2 / 6 (33.33%)	29 / 208 (13.94%)	0 / 7 (0.00%)
occurrences (all)	2	35	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Muscular weakness			
subjects affected / exposed	1 / 6 (16.67%)	10 / 208 (4.81%)	0 / 7 (0.00%)
occurrences (all)	1	10	0
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	12 / 208 (5.77%)	1 / 7 (14.29%)
occurrences (all)	1	17	1
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences (all)	1	5	0
Pain in jaw			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	15 / 208 (7.21%)	0 / 7 (0.00%)
occurrences (all)	0	16	0
Campylobacter gastroenteritis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Escherichia bacteraemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Herpes simplex			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	8 / 208 (3.85%)	0 / 7 (0.00%)
occurrences (all)	0	9	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	9 / 208 (4.33%)	0 / 7 (0.00%)
occurrences (all)	0	11	0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences (all)	0	5	0
Pneumonia klebsiella			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	11 / 208 (5.29%)	2 / 7 (28.57%)
occurrences (all)	1	14	2
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	17 / 208 (8.17%)	0 / 7 (0.00%)
occurrences (all)	0	24	0
Vulvovaginal candidiasis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Lung infection			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	1 / 7 (14.29%)
occurrences (all)	0	6	1
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences (all)	0	6	0
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cellulitis orbital			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Enterovirus infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Erysipelas			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			

subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	7	0
Sinusitis bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Staphylococcal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Clostridium difficile infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)	41 / 208 (19.71%)	2 / 7 (28.57%)
occurrences (all)	1	44	2
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	12	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	4	0

Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	33 / 208 (15.87%)	1 / 7 (14.29%)
occurrences (all)	0	43	1
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	10 / 208 (4.81%)	0 / 7 (0.00%)
occurrences (all)	0	12	0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	6 / 208 (2.88%)	0 / 7 (0.00%)
occurrences (all)	0	8	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Gout			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Hyperphosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Hypochloraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0

Non-serious adverse events	Venetoclax+G-CHOP 400 mg	Venetoclax+G-CHOP 600 mg	Venetoclax+G-CHOP 800 mg A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Papillary thyroid cancer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lung neoplasm malignant			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Thrombophlebitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 7 (28.57%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	2	2	4
Gait disturbance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	3 / 7 (42.86%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Non−cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	3 / 6 (50.00%)
occurrences (all)	1	0	3
Pyrexia			
subjects affected / exposed	5 / 7 (71.43%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	7	2	2
Unevaluable event			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal dryness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 7 (42.86%)	0 / 6 (0.00%)	3 / 6 (50.00%)
occurrences (all)	3	0	5
Dyspnoea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	4
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sinus pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Vocal cord dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Mood swings			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Investigations			
Blood potassium increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Computerised tomogram thorax abnormal			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Infusion related reaction			
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	1	2	3
Muscle strain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tracheal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Ichthyosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Carotid sinus syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	3 / 7 (42.86%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	3	1	2
Headache			
subjects affected / exposed	3 / 7 (42.86%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Memory impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Paraesthesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ageusia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Post herpetic neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	5 / 6 (83.33%)
occurrences (all)	1	4	8
Febrile neutropenia			
subjects affected / exposed	4 / 7 (57.14%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	7	0	1
Haemolytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	4 / 7 (57.14%)	5 / 6 (83.33%)	6 / 6 (100.00%)
occurrences (all)	17	13	12
Pancytopenia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	4 / 6 (66.67%)
occurrences (all)	7	6	14
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Abdominal pain			

subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	3 / 6 (50.00%)
occurrences (all)	1	1	4
Abdominal pain upper			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	3	2	2
Diarrhoea			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	6	3	4
Dyspepsia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 7 (57.14%)	3 / 6 (50.00%)	5 / 6 (83.33%)
occurrences (all)	7	4	10
Oral pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proctalgia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 7 (57.14%)	0 / 6 (0.00%)	4 / 6 (66.67%)
occurrences (all)	8	0	6
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dental caries			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dental cyst			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Flatulence			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastric ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nail discolouration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pigmentation disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	2
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo−papular			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Ecchymosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nail disorder			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Purpura			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	3	3	0
Bone pain			
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Back pain			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Campylobacter gastroenteritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pneumonia klebsiella			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	2
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cellulitis orbital			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Enterovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Furuncle			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oral fungal infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Sinusitis bacterial			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Clostridium difficile infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	2	1	2
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypokalaemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Fluid retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gout			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypochloraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Venetoclax+G-CHOP 800 mg B		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Papillary thyroid cancer subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Squamous cell carcinoma subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Lung neoplasm malignant subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Vascular disorders Hot flush subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Hypotension subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Chest pain subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Chills subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Fatigue subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Gait disturbance subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Malaise			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Non−cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Unevaluable event			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Feeling abnormal			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Infusion site extravasation			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Hypersensitivity			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Testicular pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vaginal discharge			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vulvovaginal dryness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hiccups			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Sinus pain			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vocal cord dysfunction			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Mood swings			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Investigations			
Blood potassium increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood magnesium decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Computerised tomogram thorax abnormal			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Ejection fraction decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Urine output decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Infusion related reaction subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 4		
Muscle strain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Thermal burn subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Tracheal obstruction subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Fall subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Procedural pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Congenital, familial and genetic disorders Ichthyosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Atrial fibrillation subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Palpitations subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Tachycardia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Cardiac failure			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Carotid sinus syndrome			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Cognitive disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Dysgeusia			
subjects affected / exposed	4 / 6 (66.67%)		
occurrences (all)	4		
Headache			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	3		
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Syncope				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Ageusia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypoaesthesia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Lethargy				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Peripheral motor neuropathy				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Post herpetic neuralgia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	4 / 6 (66.67%)			
occurrences (all)	5			
Febrile neutropenia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Haemolytic anaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Leukopenia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Neutropenia				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	10			
Pancytopenia				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	5		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Photophobia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Abdominal pain			

subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Abdominal pain upper				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Diarrhoea				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Gingival pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Haemorrhoids				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Mouth ulceration				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	4 / 6 (66.67%)			
occurrences (all)	6			
Oral pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Proctalgia				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dental caries			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dental cyst			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastric ulcer			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nail discolouration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pigmentation disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Rash maculo−papular			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nail disorder			

subjects affected / exposed occurrences (all) Purpura subjects affected / exposed occurrences (all) Skin hyperpigmentation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 1 / 6 (16.67%) 1 1 / 6 (16.67%) 1		
Renal and urinary disorders Bladder hypertrophy subjects affected / exposed occurrences (all) Dysuria subjects affected / exposed occurrences (all) Urinary tract pain subjects affected / exposed occurrences (all) Haematuria subjects affected / exposed occurrences (all) Nocturia subjects affected / exposed occurrences (all) Pollakiuria subjects affected / exposed occurrences (all) Renal failure subjects affected / exposed occurrences (all) Urinary incontinence subjects affected / exposed occurrences (all)	 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 1 / 6 (16.67%) 1 0 / 6 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Campylobacter gastroenteritis			

subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Conjunctivitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Escherichia bacteraemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Herpes simplex				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Oral candidiasis				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pneumonia klebsiella				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pseudomonal bacteraemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Urinary tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Vulvovaginal candidiasis				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Device related infection				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Lung infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Candida infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Cellulitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Cellulitis orbital				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Enterovirus infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Erysipelas				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Furuncle				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Oral fungal infection				

subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Sinusitis bacterial			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Staphylococcal infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Clostridium difficile infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tumour lysis syndrome			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hyperphosphataemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypochloraemia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 January 2014	Changes that allow for symmetry in the treatment of patients receiving rituximab or obinutuzumab in case of hepatitis B reactivation. Changes to clarify that either antibody should be held in case of serious infection. clarification that patients with mantle cell lymphoma (MCL) and small lymphocytic lymphoma (SLL) were not eligible for the dose escalation portion of the study for safety reasons.
23 May 2014	Changes amended following identification of higher incidence of thrombocytopenia and hemorrhagic events in patients receiving obinutuzumab. Guidelines for management of patients with thrombocytopenia, especially during the first cycle have been added.
01 October 2014	An exploratory analysis of minimal residual disease has been added. Language has been added indicating the possibility of continued cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) treatment for up to eight cycles in selected patients who are tolerating therapy well and for whom it is felt by the investigator to be appropriate. Response criteria have been updated to be consistent with the 2014 Lugano Classification. Safety language has been updated.
24 April 2015	GDC-0199 dosing schedule updated. Characterization of the pharmacokinetics of the cyclophosphamide, doxorubicin and vincristine (CHO) components was deleted from the Pharmacokinetic Objectives as detailed characterization cannot be achieved with the current PK sampling scheme.
07 December 2015	An interim safety analysis has been added after 20 patients in the R-CHOP arm in the Phase II portion of the study have completed two cycles of treatment in order to confirm the safety and tolerability of the combination therapy at the venetoclax. The primary objectives of Phase II of the study have been modified to include assessment of efficacy of R-CHOP+ Venetoclax in patients with co-expression of both Bcl-2 and c-Myc. The term PET/CT will be replaced with PET-CT throughout the protocol.
10 October 2016	Venetoclax nonclinical toxicology section updated based on recent data findings. Twelve month Progression Free Survival (PFS) was added as a secondary efficacy objective. Information was added regarding the decision to not open Arm B in Phase II in DLBCL on the basis of information from the GOYA study results.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported