

**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	28 June 2019

Results information

Result version number	v3 (current)
This version publication date	17 June 2020
First version publication date	12 July 2018
Version creation reason	

Trial information**Trial identification**

Sponsor protocol code	GO27878
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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
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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
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Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 June 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 June 2019
Was the trial ended prematurely?	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 consisted of 2 stages: a dose-finding Phase Ib stage and a Phase II expansion stage. In the Phase I portion of the study, participants were 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 explored 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 was 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:

On 17 July 2016, Roche/Genentech as the sponsor of Study BO21005 (Goya study), a Phase III study that evaluated G CHOP versus R-CHOP in 1L DLBCL, informed through a press release that the primary endpoint of investigator-assessed PFS was not met. Given these results, Arm B (venetoclax + G-CHOP) was not expanded in Phase II in participants who are first-line with DLBCL

Actual start date of recruitment	17 November 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
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:

At start the trial had a randomised-controlled component, until July 2016 once the arm B (Gazyva) got closed following the publication of results of another trial. Since July 2016, the trial was single-arm, not randomised anymore, and kept including patients in only 1 arm (Arm A, rituximab).

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 200 mg +R-CHOP

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could 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 milligram (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.

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/m²) 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/m² 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 up to Cycle 8.	
Arm title	Venetoclax 400 mg +R-CHOP
Arm description:	
Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could 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 400 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.	
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 up to Cycle 8.	
Arm title	Venetoclax 600 mg +R-CHOP
Arm description:	
Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could 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 600 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.	
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	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion, Solution for infusion
Routes of administration	Intravenous use, Intravenous use
Dosage and administration details:	
Rituximab 375 mg/m ² dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.	

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.	
Arm title	Venetoclax 800 mg +R-CHOP
Arm description:	
Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could 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 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 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	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab 375 mg/m² dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.

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/m² (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.

Arm title	Venetoclax 800 mg +R-CHOP Phase II
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Arm description:

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

Arm type	Experimental
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/m² dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.

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 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 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/m²) 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.	
Arm title	Venetoclax 200 mg +G-CHOP
Arm description:	
Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could 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 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.	
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.	
Arm title	Venetoclax 400 mg +G-CHOP
Arm description:	
Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could 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 400 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.	
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.	
Arm title	Venetoclax 600 mg +G-CHOP
Arm description:	
Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could 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 600 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.	
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	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.	
Arm title	Venetoclax 800 mg +G-CHOP A
Arm description:	
Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects who experienced ongoing response without excessive toxicity could 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 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.	
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/m² 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/m² (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

Arm title	Venetoclax 800 mg +G-CHOP B
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Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects who experienced ongoing response without excessive toxicity could 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 800 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4–8 of Cycle 1 and Days 1–5 of Cycles 2–8 during Phase I.

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/m²) 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/m² 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/m² (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 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP
Started	7	3	8
Completed	6	3	7
Not completed	1	0	1
Consent withdrawn by subject	-	-	-
Death	1	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Venetoclax 800 mg +R-CHOP	Venetoclax 800 mg +R-CHOP Phase II	Venetoclax 200 mg +G-CHOP
Started	6	208	7
Completed	3	159	5
Not completed	3	49	2
Consent withdrawn by subject	-	12	1
Death	2	33	1
Lost to follow-up	1	4	-

Number of subjects in period 1	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax 800 mg +G-CHOP A
Started	7	6	6
Completed	5	6	6
Not completed	2	0	0
Consent withdrawn by subject	-	-	-
Death	1	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Venetoclax 800 mg +G-CHOP B
Started	6
Completed	6
Not completed	0

Consent withdrawn by subject	-
Death	-
Lost to follow-up	-

Baseline characteristics

Reporting groups

Reporting group title	Venetoclax 200 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 400 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 600 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 800 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 800 mg +R-CHOP Phase II
Reporting group description: Phase II: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Subjects 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 200 mg +G-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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 400 mg +G-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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 600 mg +G-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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 800 mg +G-CHOP A
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects 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 800 mg +G-CHOP B

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects 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 values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP
Number of subjects	7	3	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	2	7
From 65-84 years	4	1	1
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	67.0	61.0	57.0
standard deviation	± 9.2	± 13.1	± 9.5
Sex: Female, Male Units: Subjects			
Female	3	2	2
Male	4	1	6
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
White	6	1	2
Unknown	1	2	6
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	1	2
Not Stated	1	2	6
Unknown	0	0	0

Reporting group values	Venetoclax 800 mg +R-CHOP	Venetoclax 800 mg +R-CHOP Phase II	Venetoclax 200 mg +G-CHOP
Number of subjects	6	208	7
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0

Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	101	5
From 65-84 years	1	106	2
85 years and over	0	1	0
Age Continuous			
Units: Years			
arithmetic mean	56.3	61.4	52.1
standard deviation	± 11.9	± 12.8	± 16.2
Sex: Female, Male			
Units: Subjects			
Female	2	94	2
Male	4	114	5
Race			
Units: Subjects			
Asian	0	5	0
Black or African American	0	4	0
Native Hawaiian or other Pacific Islande	0	3	0
White	2	154	7
Unknown	4	42	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	4	0
Not Hispanic or Latino	3	151	6
Not Stated	2	45	1
Unknown	1	8	0

Reporting group values	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax 800 mg +G-CHOP A
Number of subjects	7	6	6
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	3	3
From 65-84 years	1	3	3
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	60.9	66.7	60.5
standard deviation	± 6.3	± 4.2	± 13.7

Sex: Female, Male			
Units: Subjects			
Female	5	4	4
Male	2	2	2
Race			
Units: Subjects			
Asian	1	0	0
Black or African American	0	0	0
Native Hawaiian or other Pacific Islande	0	0	0
White	2	4	5
Unknown	4	2	1
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	4	5
Not Stated	4	1	0
Unknown	0	1	1

Reporting group values	Venetoclax 800 mg +G-CHOP B	Total	
Number of subjects	6	264	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	2	137	
From 65-84 years	4	126	
85 years and over	0	1	
Age Continuous			
Units: Years			
arithmetic mean	66.8		
standard deviation	± 6.7	-	
Sex: Female, Male			
Units: Subjects			
Female	2	120	
Male	4	144	
Race			
Units: Subjects			
Asian	0	6	
Black or African American	0	4	
Native Hawaiian or other Pacific Islande	0	3	
White	4	187	
Unknown	2	64	
Ethnicity			
Units: Subjects			

Hispanic or Latino	0	4	
Not Hispanic or Latino	6	187	
Not Stated	0	62	
Unknown	0	11	

End points

End points reporting groups

Reporting group title	Venetoclax 200 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 400 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 600 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 800 mg +R-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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 800 mg +R-CHOP Phase II
Reporting group description: Phase II: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Subjects 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 200 mg +G-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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 400 mg +G-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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 600 mg +G-CHOP
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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 800 mg +G-CHOP A
Reporting group description: Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects 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 800 mg +G-CHOP B

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects 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	Safety analysis

Subject analysis set description:

One participant in Venetoclax + R-CHOP 200mg arm mistakenly received only 100 mg instead of the planned 200 mg dose and was reported in a separate arm for PK outcome measures.

Subject analysis set title	Venetoclax + G-CHOP 800 mg A+B
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received Venetoclax + G-CHOP 800 mg.

Subject analysis set title	Venetoclax + R-CHOP 800 mg Phase I and II
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received Venetoclax + R-CHOP 800 mg.

Subject analysis set title	Venetoclax PK population
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received Venetoclax and provided at least one post-treatment PK sample.

Subject analysis set title	Venetoclax 800 mg PK population
Subject analysis set type	Per protocol

Subject analysis set description:

All participants in the study, who received 800 mg venetoclax and provided at least one post-treatment PK sample for whom data were available.

Subject analysis set title	Venetoclax + R-CHOP Arm
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received Venetoclax + R-CHOP.

Subject analysis set title	Venetoclax + R-CHOP
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received Venetoclax + R-CHOP.

Subject analysis set title	Venetoclax 800 mg +R-CHOP Phase II ITT population
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All participants who were randomized into Venetoclax 800 mg +R-CHOP Phase II arm.

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

End point title	Safety: Number of Participants With Dose-Limiting Toxicities (DLTs) ^{[1][2]}
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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 \geq 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
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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: No statistical analysis provided

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

Justification: Analysis performed on specified subject analysis sets

End point values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 800 mg +R-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	8	6
Units: Participants	1	0	1	0

End point values	Venetoclax 200 mg +G-CHOP	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax 800 mg +G-CHOP A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	6	6
Units: Participants	2	1	1	0

End point values	Venetoclax 800 mg +G-CHOP B			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Previously Untreated DLBCL 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 Previously Untreated DLBCL 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) ^[3]
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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 \leq mediastinum; 3) uptake $<$ mediastinum but \leq 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 6 months)	
Notes:	
[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: No statistical analysis provided	

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

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With CR Defined by PET/CT Scan in Previously Untreated DLBCL Coexpressing Both Bcl2 and cMyc Proteins (DE-DLBCL) Participants Assessed by IRC

End point title	Percentage of Participants With CR Defined by PET/CT Scan in Previously Untreated DLBCL Coexpressing Both Bcl2 and cMyc Proteins (DE-DLBCL) Participants Assessed by IRC ^[4]
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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 \leq mediastinum; 3) uptake $<$ mediastinum but \leq 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 6 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: No statistical analysis provided	

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

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) ^[5]
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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
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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)

Notes:

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

Justification: Analysis performed on specified subject analysis sets

End point values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 200 mg +G-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	8	7
Units: hr*mcg/mL				
arithmetic mean (standard deviation)	2.51 (± 0.97)	3.87 (± 2.41)	3.70 (± 1.59)	2.55 (± 1.13)

End point values	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax + R-CHOP 100 mg	Venetoclax + G-CHOP 800 mg A+B
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	1	10
Units: hr*mcg/mL				
arithmetic mean (standard deviation)	4.33 (± 1.31)	5.13 (± 2.41)	0.66 (± 9999)	6.20 (± 1.71)

End point values	Venetoclax + R-CHOP 800 mg Phase I and II			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: hr*mcg/mL				

arithmetic mean (standard deviation)	4.51 (\pm 2.32)			
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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) ^[6]
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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
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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)

Notes:

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

Justification: Analysis performed on specified subject analysis sets

End point values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 200 mg +G-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	8	7
Units: Hour				
arithmetic mean (standard deviation)	4.59 (\pm 1.08)	6.50 (\pm 1.91)	5.52 (\pm 2.07)	5.72 (\pm 1.42)

End point values	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax + R-CHOP 100 mg	Venetoclax + G-CHOP 800 mg A+B
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	1	10
Units: Hour				
arithmetic mean (standard deviation)	6.56 (\pm 1.51)	5.30 (\pm 2.38)	4.0 (\pm 9999)	5.79 (\pm 1.47)

End point values	Venetoclax + R-CHOP 800 mg Phase I and II			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: Hour				

arithmetic mean (standard deviation)	5.53 (\pm 1.55)			
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Statistical analyses

No statistical analyses for this end point

Secondary: Venetoclax Plasma PK: Maximum Observed Plasma Concentration (C_{max})

End point title	Venetoclax Plasma PK: Maximum Observed Plasma Concentration (C _{max}) ^[7]
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End point description:

C_{max} 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
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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)

Notes:

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

Justification: Analysis performed on specified subject analysis sets

End point values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 200 mg +G-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	8	7
Units: Ug/ML				
arithmetic mean (standard deviation)	0.58 (\pm 0.32)	0.92 (\pm 0.64)	0.85 (\pm 0.33)	0.52 (\pm 0.21)

End point values	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax + R-CHOP 100 mg	Venetoclax + G-CHOP 800 mg A+B
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	1	10
Units: Ug/ML				
arithmetic mean (standard deviation)	1.26 (\pm 0.3)	1.0 (\pm 0.58)	0.09 (\pm 9999)	1.54 (\pm 0.37)

End point values	Venetoclax + R-CHOP 800 mg Phase I and II			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: Ug/ML				

arithmetic mean (standard deviation)	1.15 (\pm 0.48)			
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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 ^[8]
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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
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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)

Notes:

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

Justification: Analysis performed on specified subject analysis sets

End point values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 200 mg +G-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	7
Units: mcg/mL				
arithmetic mean (standard deviation)	0.522 (\pm 0.441)	0.253 (\pm 0.247)	0.387 (\pm 0.141)	0.134 (\pm 0.107)

End point values	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax + R-CHOP 100 mg	Venetoclax + G-CHOP 800 mg A+B
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	1	6
Units: mcg/mL				
arithmetic mean (standard deviation)	0.395 (\pm 0.381)	0.612 (\pm 0.535)	0.0714 (\pm 9999)	0.628 (\pm 0.395)

End point values	Venetoclax + R-CHOP 800 mg Phase I and II			
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Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: mcg/mL				
arithmetic mean (standard deviation)	0.640 (± 0.451)			

Statistical analyses

No statistical analyses for this end point

Secondary: Prednisone Plasma PK: AUC

End point title	Prednisone Plasma PK: AUC
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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
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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 PK population			
Subject group type	Subject analysis set			
Number of subjects analysed	52			
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
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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
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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 PK population			
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 Prednisone 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 PK population			
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 800 mg PK population			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: mcg/mL				
arithmetic mean (standard deviation)	173 (\pm 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 800 mg PK population			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: mcg/mL				
arithmetic mean (standard deviation)	26.1 (\pm 13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Obinutuzumab PK: Cmax

End point title	Obinutuzumab PK: Cmax
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End point description:

C_{max} 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
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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 800 mg PK population			
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: C_{max}

End point title	Cyclophosphamide PK: C _{max}
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End point description:

C_{max} 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
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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 PK population			
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
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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
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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 PK population			
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
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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
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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 PK population			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: mcg/mL				
arithmetic mean (standard deviation)	54.0 (± 44.6)			

Statistical analyses

Secondary: Percentage of Participants With Objective Response Defined as Partial Response (PR) or Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET/CT) Using the Modified Lugano Classification assessed by IRC

End point title	Percentage of Participants With Objective Response Defined as Partial Response (PR) or Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET/CT) Using the Modified Lugano Classification assessed by IRC
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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
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End point timeframe:

Baseline to end of treatment (up to approximately 6 months)

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

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 ^[9]
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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: $\geq 50\%$ decrease in SPD of up to 6 target measurable 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
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End point timeframe:

Month 12

Notes:

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

Justification: Analysis performed on specified subject analysis sets

End point values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 800 mg +R-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	8	6
Units: Percentage of Participants				
number (confidence interval 95%)	85.71 (59.79 to 100)	100 (100 to 100)	87.50 (64.58 to 100)	66.67 (28.95 to 100)

End point values	Venetoclax 200 mg +G-CHOP	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP	Venetoclax 800 mg +G-CHOP A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	6	6
Units: Percentage of Participants				
number (confidence interval 95%)	100 (100 to 100)	75.00 (32.75 to 100)	100 (100 to 100)	100 (100 to 100)

End point values	Venetoclax 800 mg +G-CHOP B	Venetoclax 800 mg +R-CHOP Phase II ITT population		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	6	211		
Units: Percentage of Participants				
number (confidence interval 95%)	100 (100 to 100)	88.99 (82.65 to 92.10)		

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
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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 end of treatment (approx. 6 months)	

End point values	Venetoclax 800 mg +R-CHOP Phase II ITT population			
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 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 800 mg +R-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	8	6
Units: Percentage of Participants				
number (not applicable)	100.00	100.00	100.00	100.00

End point values	Venetoclax 800 mg +R-CHOP Phase II	Venetoclax 200 mg +G-CHOP	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	206	7	7	6
Units: Percentage of Participants				

number (not applicable)	99.0	100.00	100.00	100.00
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End point values	Venetoclax 800 mg +G-CHOP A	Venetoclax 800 mg +G-CHOP B		
Subject group type	Reporting group	Reporting group		
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 $\geq 90\%$. 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 + R-CHOP		
Subject group type	Subject analysis set	Subject analysis set		
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
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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 8 (cycle length = 21 days)	

End point values	Venetoclax 200 mg +R-CHOP	Venetoclax 400 mg +R-CHOP	Venetoclax 600 mg +R-CHOP	Venetoclax 800 mg +R-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	8	6
Units: Percentage of Participants				
number (not applicable)				
<80%	71.4	0.00	12.5	0.00
80-<85%	0.00	0.00	12.5	0.00
85-<90%	0.00	0.00	12.5	0.00
>=90%	28.6	100	62.5	100

End point values	Venetoclax 800 mg +R-CHOP Phase II	Venetoclax 200 mg +G-CHOP	Venetoclax 400 mg +G-CHOP	Venetoclax 600 mg +G-CHOP
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	208	7	7	6
Units: Percentage of Participants				
number (not applicable)				
<80%	26.0	100	14.3	50.0
80-<85%	3.4	0.00	14.3	16.7
85-<90%	2.9	0.00	0.00	0.00
>=90%	67.6	0.00	71.4	33.3

End point values	Venetoclax 800 mg +G-CHOP A	Venetoclax 800 mg +G-CHOP B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Percentage of Participants				
number (not applicable)				
<80%	83.3	100		
80-<85%	0.00	0.00		
85-<90%	16.7	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 67 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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Venetoclax+R-CHOP 200 mg
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase II: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects 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
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Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects 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%)	4 / 8 (50.00%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE MYELOID LEUKAEMIA			
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
ADENOLYMPHOMA			
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
GLIOBLASTOMA			
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
HISTIOCYTOSIS			
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 NEOPLASM MALIGNANT			
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
MYELODYSPLASTIC 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
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			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
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
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
INTERSTITIAL LUNG DISEASE			
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			
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			
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
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
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
CARDIAC FAILURE CONGESTIVE			
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
LEFT VENTRICULAR 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
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	2 / 2
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
BACTERIAL 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
BRONCHITIS			
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
CLOSTRIDIUM DIFFICILE 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
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
EMPHYEMA			
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			

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
OOPHORITIS			
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 JIROVECI 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 JIROVECI 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
RECTAL ABSCESS			
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%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
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
SIALOADENITIS			
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
STAPHYLOCOCCAL 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
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
VASCULAR DEVICE 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%)	116 / 208 (55.77%)	5 / 7 (71.43%)
number of deaths (all causes)	2	33	1
number of deaths resulting from adverse events	0	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE MYELOID LEUKAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	2 / 2	0 / 0
ADENOLYMPHOMA			
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
GLIOBLASTOMA			

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
HISTIOCYTOSIS			
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
LUNG NEOPLASM MALIGNANT			
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
MYELODYSPLASTIC SYNDROME			
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
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			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
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
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
INTERSTITIAL LUNG DISEASE			
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			
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%)	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
Injury, poisoning and procedural complications			
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
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
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%)	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
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
CARDIAC FAILURE CONGESTIVE			
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
LEFT VENTRICULAR 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
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%)	57 / 208 (27.40%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	3 / 3	85 / 89	1 / 1
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%)	19 / 208 (9.13%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	24 / 24	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
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
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
BACTERIAL 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
BRONCHITIS			
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
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
CLOSTRIDIUM DIFFICILE 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
DEVICE RELATED 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
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
EMPHYSEMA			

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			
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	2 / 5	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%)	3 / 208 (1.44%)	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
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
OOPHORITIS			
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 JIROVECI 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 JIROVECI 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%)	9 / 208 (4.33%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	7 / 9	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%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
RECTAL ABSCESS			
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
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
SEPSIS			
subjects affected / exposed	1 / 6 (16.67%)	6 / 208 (2.88%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	5 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
SIALOADENITIS			

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
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
STAPHYLOCOCCAL 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
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%)	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
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
VASCULAR DEVICE 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
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 400 mg	Venetoclax+G-CHOP 600 mg	Venetoclax+G-CHOP 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)	1	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE MYELOID LEUKAEMIA			
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
ADENOLYMPHOMA			
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
GLIOBLASTOMA			
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
HISTIOCYTOSIS			
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
LUNG NEOPLASM MALIGNANT			
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
MYELOYDYSPLASTIC 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			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
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
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
DYSпноEA			
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
INTERSTITIAL LUNG DISEASE			
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	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
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			
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			
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
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
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

CARDIAC FAILURE CONGESTIVE			
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
LEFT VENTRICULAR 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
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 occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
ATYPICAL PNEUMONIA subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
BACTERIAL SEPSIS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
BRONCHITIS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
CELLULITIS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
CLOSTRIDIUM COLITIS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
CLOSTRIDIUM DIFFICILE INFECTION subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0
DEVICE RELATED INFECTION subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 6 (0.00%) 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
EMPYEMA			
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
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			
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
OOPHORITIS			
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
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 JIROVECI 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 JIROVECI 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	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 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
RECTAL ABSCESS			
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
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
SIALOADENITIS			
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
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
STAPHYLOCOCCAL 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
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
VASCULAR DEVICE 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	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE MYELOID LEUKAEMIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ADENOLYMPHOMA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
GLIOBLASTOMA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HISTIOCYTOSIS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
LUNG NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
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			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
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		
INTERSTITIAL LUNG DISEASE			
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			
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			
CONTUSION			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
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		
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			
CARDIAC FAILURE CONGESTIVE				
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			
LEFT VENTRICULAR FAILURE				
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	1 / 6 (16.67%)		
occurrences causally related to treatment / all	1 / 1		
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		
BACTERIAL SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BRONCHITIS			
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		
CLOSTRIDIUM DIFFICILE INFECTION			

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			
EMPYEMA				
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				
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			
OOPHORITIS				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
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	1 / 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			
RECTAL ABSCESS				
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			
SEPSIS				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SIALOADENITIS				
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			
STAPHYLOCOCCAL SEPSIS				
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		
VASCULAR DEVICE 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)			
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
SQUAMOUS CELL CARCINOMA OF SKIN			
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%)	2 / 8 (25.00%)
occurrences (all)	2	2	2

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
FEELING ABNORMAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	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
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

PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
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
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	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	2 / 7 (28.57%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	3	2	0

DYSпноEA EXERTIONAL			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
EPISTAXIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
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
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
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
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
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

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			
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
BLOOD POTASSIUM INCREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	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

WEIGHT DECREASED subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 3	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
WEIGHT INCREASED subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
WHITE BLOOD CELL COUNT DECREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Injury, poisoning and procedural complications FALL subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
HAND FRACTURE subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
INFUSION RELATED REACTION subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 3 (66.67%) 2	1 / 8 (12.50%) 1
MUSCLE STRAIN subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
PROCEDURAL PAIN subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
THERMAL BURN subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
TRACHEAL OBSTRUCTION subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Congenital, familial and genetic disorders ICHTHYOSIS subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 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
CARDIAC FAILURE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
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
Nervous system disorders			
AGEUSIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
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%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
HEADACHE			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	3
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
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 MOTOR NEUROPATHY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	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
POST HERPETIC NEURALGIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
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
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%)	6 / 8 (75.00%)
occurrences (all)	9	8	18
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%)	3 / 8 (37.50%)
occurrences (all)	7	2	5
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
EYE PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
PHOTOPHOBIA			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
VITREOUS FLOATERS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
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
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
DIARRHOEA			
subjects affected / exposed	3 / 7 (42.86%)	2 / 3 (66.67%)	2 / 8 (25.00%)
occurrences (all)	10	4	2
DRY MOUTH			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

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
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
GASTROESOPHAGEAL 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
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
ECCHYMOSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	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
PURPURA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	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
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
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
URINARY TRACT PAIN			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	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
BACK PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
BONE PAIN			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
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
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	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 occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 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
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
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
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
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
HERPES SIMPLEX			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
HERPES ZOSTER			
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
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	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	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
ORAL HERPES			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PNEUMOCYSTIS JIROVECI 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
PSEUDOMONAL BACTERAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
RHINITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SEPSIS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	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
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
VASCULAR DEVICE 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
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
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
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
HYPERKALAEMIA			
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
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
HYPOCHLORAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	3 / 7 (42.86%)	1 / 3 (33.33%)	2 / 8 (25.00%)
occurrences (all)	4	1	2

HYPOMAGNEAEMIA			
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

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%)	204 / 208 (98.08%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA OF SKIN			
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%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	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%)	12 / 208 (5.77%)	0 / 7 (0.00%)
occurrences (all)	0	12	0
CHILLS			
subjects affected / exposed	1 / 6 (16.67%)	12 / 208 (5.77%)	0 / 7 (0.00%)
occurrences (all)	1	15	0
FATIGUE			
subjects affected / exposed	2 / 6 (33.33%)	81 / 208 (38.94%)	5 / 7 (71.43%)
occurrences (all)	4	104	7
FEELING ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
GAIT DISTURBANCE			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	1 / 7 (14.29%)
occurrences (all)	0	4	1
INFUSION SITE EXTRAVASATION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	1 / 7 (14.29%)
occurrences (all)	0	5	2
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 6 (16.67%)	19 / 208 (9.13%)	1 / 7 (14.29%)
occurrences (all)	1	28	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 occurrences (all)	0 / 6 (0.00%) 0	23 / 208 (11.06%) 26	0 / 7 (0.00%) 0
PAIN subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	7 / 208 (3.37%) 8	1 / 7 (14.29%) 1
PYREXIA subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	50 / 208 (24.04%) 68	0 / 7 (0.00%) 0
UNEVALUABLE EVENT subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
Immune system disorders HYPERSENSITIVITY subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
HYPOGAMMAGLOBULINAEMIA subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 208 (0.48%) 1	0 / 7 (0.00%) 0
Reproductive system and breast disorders BREAST PAIN subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
TESTICULAR PAIN subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
VAGINAL DISCHARGE subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
VULVOVAGINAL DRYNESS subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders COUGH subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	51 / 208 (24.52%) 67	3 / 7 (42.86%) 3

DYSпноEA			
subjects affected / exposed	1 / 6 (16.67%)	22 / 208 (10.58%)	0 / 7 (0.00%)
occurrences (all)	1	24	0
DYSпноEA EXERTIONAL			
subjects affected / exposed	1 / 6 (16.67%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	1	4	0
EPISTAXIS			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
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
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	10 / 208 (4.81%)	1 / 7 (14.29%)
occurrences (all)	0	13	1
PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			
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%)	8 / 208 (3.85%)	0 / 7 (0.00%)
occurrences (all)	0	8	0
RHINORRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	11 / 208 (5.29%)	1 / 7 (14.29%)
occurrences (all)	0	11	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 occurrences (all)	0 / 6 (0.00%) 0	1 / 208 (0.48%) 1	0 / 7 (0.00%) 0
Psychiatric disorders ANXIETY subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	9 / 208 (4.33%) 9	1 / 7 (14.29%) 3
DEPRESSION subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	4 / 208 (1.92%) 5	0 / 7 (0.00%) 0
INSOMNIA subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	14 / 208 (6.73%) 17	2 / 7 (28.57%) 2
MOOD SWINGS subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
Investigations ALANINE AMINOTRANSFERASE INCREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 208 (0.48%) 1	1 / 7 (14.29%) 1
ASPARTATE AMINOTRANSFERASE INCREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	1 / 7 (14.29%) 1
BLOOD MAGNESIUM DECREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
BLOOD POTASSIUM INCREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
COMPUTERISED TOMOGRAM THORAX ABNORMAL subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
EJECTION FRACTION DECREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 208 (0.96%) 2	1 / 7 (14.29%) 1

URINE OUTPUT DECREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	1 / 7 (14.29%) 1
WEIGHT DECREASED subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	32 / 208 (15.38%) 33	0 / 7 (0.00%) 0
WEIGHT INCREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	3 / 208 (1.44%) 3	0 / 7 (0.00%) 0
WHITE BLOOD CELL COUNT DECREASED subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	1 / 7 (14.29%) 1
Injury, poisoning and procedural complications			
FALL subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	4 / 208 (1.92%) 4	0 / 7 (0.00%) 0
HAND FRACTURE subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
INFUSION RELATED REACTION subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 3	44 / 208 (21.15%) 48	4 / 7 (57.14%) 4
MUSCLE STRAIN subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
PROCEDURAL PAIN subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
THERMAL BURN subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
TRACHEAL OBSTRUCTION subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
Congenital, familial and genetic disorders			

ICHTHYOSIS subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac disorders ANGINA PECTORIS subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
ATRIAL FIBRILLATION subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	7 / 208 (3.37%) 8	1 / 7 (14.29%) 1
CARDIAC FAILURE subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 208 (0.48%) 1	1 / 7 (14.29%) 1
PALPITATIONS subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	8 / 208 (3.85%) 8	0 / 7 (0.00%) 0
TACHYCARDIA subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	3 / 208 (1.44%) 3	0 / 7 (0.00%) 0
Nervous system disorders AGEUSIA subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	1 / 7 (14.29%) 1
CAROTID SINUS SYNDROME subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
COGNITIVE DISORDER subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 2	0 / 208 (0.00%) 0	0 / 7 (0.00%) 0
DISTURBANCE IN ATTENTION subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 208 (0.48%) 1	1 / 7 (14.29%) 1
DIZZINESS subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	24 / 208 (11.54%) 33	1 / 7 (14.29%) 1
DYSGEUSIA			

subjects affected / exposed	1 / 6 (16.67%)	19 / 208 (9.13%)	1 / 7 (14.29%)
occurrences (all)	1	19	1
HEADACHE			
subjects affected / exposed	1 / 6 (16.67%)	28 / 208 (13.46%)	3 / 7 (42.86%)
occurrences (all)	1	31	5
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
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	3 / 6 (50.00%)	28 / 208 (13.46%)	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	26	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	2 / 6 (33.33%)	14 / 208 (6.73%)	0 / 7 (0.00%)
occurrences (all)	2	14	0
POST HERPETIC NEURALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	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
Blood and lymphatic system disorders			

ANAEMIA			
subjects affected / exposed	2 / 6 (33.33%)	73 / 208 (35.10%)	1 / 7 (14.29%)
occurrences (all)	2	117	1
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 6 (16.67%)	9 / 208 (4.33%)	0 / 7 (0.00%)
occurrences (all)	3	10	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%)	23 / 208 (11.06%)	0 / 7 (0.00%)
occurrences (all)	0	47	0
NEUTROPENIA			
subjects affected / exposed	3 / 6 (50.00%)	134 / 208 (64.42%)	2 / 7 (28.57%)
occurrences (all)	10	409	2
PANCYTOPENIA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 6 (0.00%)	52 / 208 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	89	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
EYE PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
LACRIMATION INCREASED			

subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	7	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
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%)	30 / 208 (14.42%)	0 / 7 (0.00%)
occurrences (all)	1	38	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	1 / 7 (14.29%)
occurrences (all)	0	12	1
CONSTIPATION			
subjects affected / exposed	2 / 6 (33.33%)	67 / 208 (32.21%)	6 / 7 (85.71%)
occurrences (all)	2	78	7
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
DIARRHOEA			
subjects affected / exposed	3 / 6 (50.00%)	79 / 208 (37.98%)	5 / 7 (71.43%)
occurrences (all)	5	133	5

DRY MOUTH			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences (all)	0	5	0
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
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
GASTROESOPHAGEAL 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%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	7	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%)	24 / 208 (11.54%)	0 / 7 (0.00%)
occurrences (all)	2	29	0
TOOTHACHE			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
VOMITING			
subjects affected / exposed	2 / 6 (33.33%)	64 / 208 (30.77%)	5 / 7 (71.43%)
occurrences (all)	6	111	5
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%)	28 / 208 (13.46%)	0 / 7 (0.00%)
occurrences (all)	3	29	0
DRY SKIN			
subjects affected / exposed	0 / 6 (0.00%)	8 / 208 (3.85%)	0 / 7 (0.00%)
occurrences (all)	0	9	0
ECCHYMOSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	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
PURPURA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	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%)	5 / 208 (2.40%)	1 / 7 (14.29%)
occurrences (all)	1	5	1
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
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

POLLAKEURIA			
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
URINARY TRACT PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	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
BACK PAIN			
subjects affected / exposed	2 / 6 (33.33%)	29 / 208 (13.94%)	0 / 7 (0.00%)
occurrences (all)	2	34	0
BONE PAIN			
subjects affected / exposed	1 / 6 (16.67%)	9 / 208 (4.33%)	2 / 7 (28.57%)
occurrences (all)	1	10	2
MUSCLE SPASMS			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences (all)	0	5	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 6 (16.67%)	10 / 208 (4.81%)	0 / 7 (0.00%)
occurrences (all)	1	10	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
MYALGIA			
subjects affected / exposed	1 / 6 (16.67%)	12 / 208 (5.77%)	1 / 7 (14.29%)
occurrences (all)	1	18	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
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%)	16 / 208 (7.69%)	0 / 7 (0.00%)
occurrences (all)	0	18	0
CAMPYLOBACTER GASTROENTERITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	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%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	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
HERPES SIMPLEX			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
HERPES ZOSTER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	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%)	4 / 208 (1.92%)	1 / 7 (14.29%)
occurrences (all)	0	5	1
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%)	8 / 208 (3.85%)	0 / 7 (0.00%)
occurrences (all)	0	9	0
ORAL FUNGAL INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	5 / 208 (2.40%)	0 / 7 (0.00%)
occurrences (all)	0	6	0
PNEUMOCYSTIS JIROVECI 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
PSEUDOMONAL BACTERAEemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	7	0
SEPSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	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
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 6 (16.67%)	12 / 208 (5.77%)	2 / 7 (28.57%)
occurrences (all)	1	15	2
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	16 / 208 (7.69%)	0 / 7 (0.00%)
occurrences (all)	0	22	0
VASCULAR DEVICE 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
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 6 (16.67%)	42 / 208 (20.19%)	2 / 7 (28.57%)
occurrences (all)	1	45	2
DEHYDRATION			
subjects affected / exposed	0 / 6 (0.00%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	11	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
HYPERKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	4 / 208 (1.92%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
HYPERURICAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	2 / 208 (0.96%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	3 / 208 (1.44%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
HYPOCHLORAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 208 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			

subjects affected / exposed	0 / 6 (0.00%)	35 / 208 (16.83%)	1 / 7 (14.29%)
occurrences (all)	0	44	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%)	7 / 208 (3.37%)	0 / 7 (0.00%)
occurrences (all)	0	9	0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 6 (0.00%)	1 / 208 (0.48%)	0 / 7 (0.00%)
occurrences (all)	0	1	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)			
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	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
FEELING ABNORMAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
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
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
PAIN			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
PYREXIA			
subjects affected / exposed	5 / 7 (71.43%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	7	2	1
UNEVALUABLE EVENT			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOGAMMAGLOBULINAEMIA			
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	2 / 7 (28.57%)	0 / 6 (0.00%)	3 / 6 (50.00%)
occurrences (all)	2	0	5
DYSпноEA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
DYSпноEA EXERTIONAL			
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
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
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
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 occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
WHEEZING subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Psychiatric disorders			
ANXIETY subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
DEPRESSION subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
INSOMNIA subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 3	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
MOOD SWINGS subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
ASPARTATE AMINOTRANSFERASE INCREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
BLOOD MAGNESIUM DECREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0
BLOOD POTASSIUM INCREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
COMPUTERISED TOMOGRAPH THORAX ABNORMAL subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0

EJECTION FRACTION DECREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
URINE OUTPUT DECREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
WEIGHT DECREASED subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	2 / 6 (33.33%) 2
WEIGHT INCREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
WHITE BLOOD CELL COUNT DECREASED subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Injury, poisoning and procedural complications			
FALL subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
HAND FRACTURE subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
INFUSION RELATED REACTION subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 6 (33.33%) 2	2 / 6 (33.33%) 3
MUSCLE STRAIN subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
PROCEDURAL PAIN subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
THERMAL BURN subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
TRACHEAL OBSTRUCTION			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Congenital, familial and genetic disorders ICHTHYOSIS subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Cardiac disorders ANGINA PECTORIS subjects affected / exposed occurrences (all) ATRIAL FIBRILLATION subjects affected / exposed occurrences (all) CARDIAC FAILURE subjects affected / exposed occurrences (all) PALPITATIONS subjects affected / exposed occurrences (all) TACHYCARDIA subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 1 / 7 (14.29%) 1 0 / 7 (0.00%) 0	1 / 6 (16.67%) 1 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 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0
Nervous system disorders AGEUSIA subjects affected / exposed occurrences (all) CAROTID SINUS SYNDROME subjects affected / exposed occurrences (all) COGNITIVE DISORDER subjects affected / exposed occurrences (all) DISTURBANCE IN ATTENTION subjects affected / exposed occurrences (all) DIZZINESS	0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (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 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0

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
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
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 MOTOR NEUROPATHY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
POST HERPETIC NEURALGIA			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
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 occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 6 (16.67%) 4	5 / 6 (83.33%) 8
FEBRILE NEUTROPENIA			
subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 7	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
HAEMOLYTIC ANAEMIA			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
LEUKOPENIA			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0
NEUTROPENIA			
subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 17	5 / 6 (83.33%) 13	6 / 6 (100.00%) 16
PANCYTOPENIA			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
THROMBOCYTOPENIA			
subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 7	2 / 6 (33.33%) 6	4 / 6 (66.67%) 15
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
TINNITUS			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Eye disorders			
DRY EYE			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
EYE PAIN			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
LACRIMATION INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PHOTOPHOBIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
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
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
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
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

DIARRHOEA			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	6	3	4
DRY MOUTH			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
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
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
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
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
ECCHYMOSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
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
PURPURA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
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
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
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
URINARY TRACT PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	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	2	0
BACK PAIN			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
BONE PAIN			
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	2	2	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
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
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
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
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
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVITIS			
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
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
HERPES SIMPLEX			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
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
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
ORAL FUNGAL 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

PNEUMOCYSTIS JIROVECI 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
PSEUDOMONAL BACTERAEMIA			
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
SEPSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	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
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
VASCULAR DEVICE INFECTION			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	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
VULVOVAGINAL CANDIDIASIS			
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
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
HYPERKALAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	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
HYPOCHLORAEMIA			

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

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)			
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Vascular disorders			
HOT FLUSH			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
HYPOTENSION			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
THROMBOPHLEBITIS			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
CHEST PAIN			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
CHILLS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
FATIGUE			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
FEELING ABNORMAL			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
GAIT DISTURBANCE			
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		
MALAISE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
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		
PAIN			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
PYREXIA			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
UNEVALUABLE EVENT			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
HYPOGAMMAGLOBULINAEMIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
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		
DYSпноEA			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
DYSпноEA EXERTIONAL			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
EPISTAXIS			
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		
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PLEURAL EFFUSION			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PLEURITIC PAIN			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
RHINORRHOEA			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>SINUS PAIN</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>VOCAL CORD DYSFUNCTION</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>WHEEZING</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 6 (16.67%)</p> <p>1</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p>		
<p>Psychiatric disorders</p> <p>ANXIETY</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>DEPRESSION</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>INSOMNIA</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>MOOD SWINGS</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 6 (16.67%)</p> <p>1</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>1 / 6 (16.67%)</p> <p>1</p> <p>0 / 6 (0.00%)</p> <p>0</p>		
<p>Investigations</p> <p>ALANINE AMINOTRANSFERASE INCREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ASPARTATE AMINOTRANSFERASE INCREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>BLOOD MAGNESIUM DECREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>BLOOD POTASSIUM INCREASED</p>	<p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p>		

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		
WEIGHT DECREASED			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
WEIGHT INCREASED			
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			
FALL			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
HAND FRACTURE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
INFUSION RELATED REACTION			
subjects affected / exposed	3 / 6 (50.00%)		
occurrences (all)	4		
MUSCLE STRAIN			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PROCEDURAL PAIN			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
THERMAL BURN			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
TRACHEAL OBSTRUCTION			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
ICHTHYOSIS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
CARDIAC FAILURE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PALPITATIONS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
TACHYCARDIA			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Nervous system disorders			
AGEUSIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
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		
HYPOAESTHESIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
LETHARGY			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
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 MOTOR NEUROPATHY			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
POST HERPETIC NEURALGIA			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PRESYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
SYNCOPE			
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 occurrences (all)	0 / 6 (0.00%) 0		
Eye disorders			
DRY EYE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
EYE PAIN			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
LACRIMATION INCREASED			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PHOTOPHOBIA			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
VISION BLURRED			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
VITREOUS FLOATERS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
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		
DENTAL CARIES			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
DENTAL CYST			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
DIARRHOEA			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
DRY MOUTH			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
DYSPEPSIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
DYSPHAGIA			
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		
GASTROESOPHAGEAL 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	0 / 6 (0.00%)		
occurrences (all)	0		
TOOTHACHE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
VOMITING			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
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		
ECCHYMOSIS			
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		
PURPURA			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
RASH			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
SKIN HYPERPIGMENTATION			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Renal and urinary disorders			
BLADDER HYPERTROPHY			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

DYSURIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
HAEMATURIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
NOCTURIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
POLLAKIURIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
RENAL FAILURE			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
URINARY INCONTINENCE			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
URINARY TRACT PAIN			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
BACK PAIN			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
BONE 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		
MUSCULOSKELETAL CHEST PAIN			
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		
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		
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		

CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
CONJUNCTIVITIS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
DEVICE RELATED INFECTION			
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		
HERPES SIMPLEX			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
HERPES ZOSTER			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
INFLUENZA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
LUNG INFECTION			
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		

ORAL FUNGAL INFECTION			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PNEUMOCYSTIS JIROVECI			
PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PNEUMONIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
PSEUDOMONAL BACTERAE			
MIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
RHINITIS			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
SEPSIS			
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		
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		
VASCULAR DEVICE INFECTION			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
VULVOVAGINAL CANDIDIASIS			
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		
FLUID RETENTION			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
GOUT			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
HYPERKALAEMIA			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
HYPERPHOSPHATAEMIA			
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		
HYPOCHLORAEMIA			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
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		

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/30850381>