Clinical trial results:
A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric and Young Adult Patients with Relapsed or Refractory Malignancies

Summary

EudraCT number	2017-000439-14
Trial protocol	DE NL FR
Global end of trial date	19 April 2023

Results information

Result version number	v1 (current)
This version publication date	28 October 2023
First version publication date	28 October 2023

Trial information

Trial identification

Sponsor protocol code	M13-833

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03236857
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie
Sponsor organisation address	1 North Waukegan Road, North Chicago, IL, United States, 60064
Public contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002018-PIP02-16
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This was an open-label, global, Phase 1, dose determination/cohort expansion study in pediatric and young adult subjects with relapsed or refractory malignancies. In Part 1, Dose Determination subjects with any relapsed or refractory tumor without available curative treatment options were eligible to enroll. In Part 1, Dose Escalation/De-escalation solid tumor subjects without bone marrow involvement were eligible to enroll. During Part 2 (Cohort Expansion), subjects were enrolled into one of five tumor cohorts. Four of the cohorts enrolled subjects with the following malignancies: ALL, AML, NHL, or Neuroblastoma (NBL). A fifth exploratory cohort (referred to as Other Tumors) enrolled subjects with any other tumor that expressed BCL-2 or subjects with TCF3-HLF ALL confirmed during frontline induction therapy. Subjects who had primary brain tumors and disease that was metastatic to the brain were excluded. Subjects with solid tumors enrolled in the fifth cohort were analyzed separately.

Protection of trial subjects:

Prior to the initiation of any screening or study-specific procedures, the investigator or her/his representative explained the nature of the study to the participant, parent or guardian and answered all questions regarding this study. Each informed consent was reviewed, signed and dated by the participant, parent or guardian, the person who administered the informed consent, and any other signatories according to local requirements.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	08 November 2017
Long term follow-up planned	No
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	Canada: 16
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Switzerland: 4
Country: Number of subjects enrolled	United Kingdom: 11
Country: Number of subjects enrolled	United States: 69
Worldwide total number of subjects	140
EEA total number of subjects	22

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)	9
Children (2-11 years)	74
Adolescents (12-17 years)	39
Adults (18-64 years)	18
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects underwent screening procedures within 21 days prior to initial study drug administration.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Acute Lymphoblastic Leukemia (ALL)

Arm description:

Participants with acute lymphoblastic leukemia (ALL)

Arm type	Experimental
Investigational medicinal product name	Venetoclax (n=31 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersible tablet, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Venetoclax was administered orally QD, continuously, in subjects with hematologic malignancies. Subjects who were < 2 years of age were dosed based on age and those who were 2 years and older were dosed based on weight. Subjects with liquid tumors (ALL, AML, NHL) were ramped up over 3 days as follows to achieve 800 mg adult-equivalent target dose:

Newborn to < 1 month (2.5 mg Day 1, 5 mg Day 2, and 10 mg Day 3+)
1 month to < 3 months (5 mg Day 1, 10 mg Day 2, and 25 mg Day 3+)
3 months to < 6 months (10 mg Day 1, 25 mg Day 2, and 50 mg Day 3+)
6 months to < 1 year (25 mg Day 1, 50 mg Day 2, and 100 mg Day 3+)
1 year to < 2 years (40 mg Day 1, 80 mg Day 2, and 150 mg Day 3+)

10 kg to < 20 kg (50 mg Day 1, 120 mg Day 2, and 250 mg Day 3+)
20 kg to < 30 kg (80 mg Day 1, 170 mg Day 2, and 350 mg Day 3+)
30 kg to < 45 kg (120 mg Day 1, 250 mg Day 2, and 500 mg Day 3+)
≥ 45 kg (200 mg Day 1, 400 mg Day 2, and 800 mg Day 3+)

Investigational medicinal product name	Dexamethasone (n=19 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of dexamethasone administered was 10 mg/m^2 per day (or equivalent dose of prednisone), and the dosing schedule was determined by the treating investigator.

ALL subjects were permitted to receive dexamethasone and/or vincristine and/or pegasparaginase as a chemotherapy regimen.

Investigational medicinal product name	Vincristine (n=19 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of vincristine administered was 2 mg/m^2 per day; (2 mg max; no more frequently than weekly), and the dosing schedule was determined by the treating investigator.

ALL subjects were permitted to receive dexamethasone and/or vincristine and/or pegasparaginase as a chemotherapy regimen.

Investigational medicinal product name	Pegasparaginase (n=13 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of pegasparaginase administered was 2,500 IU/m^2/dose per day (every two weeks), and the dosing schedule was determined by the treating investigator. For those with allergy or intolerance to pegasparaginase, Erwinia asparaginase was acceptable.

ALL subjects were permitted to receive dexamethasone and/or vincristine and/or pegasparaginase as a chemotherapy regimen.

Investigational medicinal product name	Cytarabine (n=10 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of cytarabine administered was 1000 mg/m^2 twice per day, and the dosing schedule was determined by the treating investigator.

ALL subjects were permitted to receive cytarabine and/or etoposide and/or pegasparaginase as a chemotherapy regimen.

Investigational medicinal product name	Etoposide (n=4 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of etoposide administered was 50 mg/m^2 per day (or 100 mg/m^2 IV daily), and the dosing schedule was determined by the treating investigator.

ALL subjects were permitted to receive cytarabine and/or etoposide and/or pegasparaginase as a chemotherapy regimen.

Investigational medicinal product name	Pegasparaginase with the Cytarabine-based regimen (n=3 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of pegasparaginase administered was 2,500 IU/m^2/dose per day (Every 2 weeks), and the dosing schedule was determined by the treating investigator. For those with allergy or intolerance to pegasparaginase, Erwinia asparaginase was acceptable.

ALL subjects were permitted to receive cytarabine and/or etoposide and/or pegasparaginase as a chemotherapy regimen.

Arm title	Acute Myeloid Leukemia (AML)

Arm description:

Participants with acute myeloid leukemia (AML)

Arm type	Experimental
Investigational medicinal product name	Venetoclax (n=37 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersible tablet, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Venetoclax was administered orally QD, continuously, in subjects with hematologic malignancies. Subjects who were < 2 years of age were dosed based on age and those who were 2 years and older were dosed based on weight. Subjects with liquid tumors (ALL, AML, NHL) were ramped up over 3 days as follows to achieve 800 mg adult-equivalent target dose:

Newborn to < 1 month (2.5 mg Day 1, 5 mg Day 2, and 10 mg Day 3+)
1 month to < 3 months (5 mg Day 1, 10 mg Day 2, and 25 mg Day 3+)
3 months to < 6 months (10 mg Day 1, 25 mg Day 2, and 50 mg Day 3+)
6 months to < 1 year (25 mg Day 1, 50 mg Day 2, and 100 mg Day 3+)
1 year to < 2 years (40 mg Day 1, 80 mg Day 2, and 150 mg Day 3+)

10 kg to < 20 kg (50 mg Day 1, 120 mg Day 2, and 250 mg Day 3+)
20 kg to < 30 kg (80 mg Day 1, 170 mg Day 2, and 350 mg Day 3+)
30 kg to < 45 kg (120 mg Day 1, 250 mg Day 2, and 500 mg Day 3+)
≥ 45 kg (200 mg Day 1, 400 mg Day 2, and 800 mg Day 3+)

Investigational medicinal product name	Cytarabine low dose (n= 1 subject)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravascular use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of cytarabine administered was 20 mg/m^2 per day (every two weeks), and the dosing schedule was determined by the treating investigator.

AML subjects were permitted to receive cytarabine or azacitidine/decitabine as a chemotherapy regimen.

Investigational medicinal product name	Cytarabine high dose (n= 9 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of cytarabine administered was 1000 mg/m^2 twice per day, and the dosing schedule was determined by the treating investigator.

AML subjects were permitted to receive cytarabine or azacitidine/decitabine as a chemotherapy regimen.

Investigational medicinal product name	Azacitidine (n= 19 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of azacitidine administered was 75 mg/m^2 per day, and the dosing schedule was determined by the treating investigator.

AML subjects were permitted to receive cytarabine or azacitidine/decitabine as a chemotherapy regimen.

Investigational medicinal product name	Decitabine (n= 5 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of decitabine administered was 20 mg/m^2 per day, and the dosing schedule was determined by the treating investigator.

AML subjects were permitted to receive cytarabine or azacitidine/decitabine as a chemotherapy regimen.

Arm title	Non-Hodgkin Lymphoma (NHL)

Arm description:

Participants with non-Hodgkin lymphoma (NHL)

Arm type	Experimental
Investigational medicinal product name	Venetoclax (n=2 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersible tablet, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Venetoclax was administered orally QD, continuously, in subjects with hematologic malignancies. Subjects who were < 2 years of age were dosed based on age and those who were 2 years and older were dosed based on weight. Subjects with liquid tumors (ALL, AML, NHL) were ramped up over 3 days as follows to achieve 800 mg adult-equivalent target dose:

Newborn to < 1 month (2.5 mg Day 1, 5 mg Day 2, and 10 mg Day 3+)
1 month to < 3 months (5 mg Day 1, 10 mg Day 2, and 25 mg Day 3+)
3 months to < 6 months (10 mg Day 1, 25 mg Day 2, and 50 mg Day 3+)
6 months to < 1 year (25 mg Day 1, 50 mg Day 2, and 100 mg Day 3+)
1 year to < 2 years (40 mg Day 1, 80 mg Day 2, and 150 mg Day 3+)

10 kg to < 20 kg (50 mg Day 1, 120 mg Day 2, and 250 mg Day 3+)
20 kg to < 30 kg (80 mg Day 1, 170 mg Day 2, and 350 mg Day 3+)
30 kg to < 45 kg (120 mg Day 1, 250 mg Day 2, and 500 mg Day 3+)
≥ 45 kg (200 mg Day 1, 400 mg Day 2, and 800 mg Day 3+)

Investigational medicinal product name	Rituximab (n= 1 subject)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of rituximab administered was 375 mg/m^2 per day (weekly), and the dosing schedule was determined by the treating investigator.

NHL subjects were permitted to receive rituximab and/or dexamethasone and/or vincristine as a chemotherapy regimen.

Investigational medicinal product name	Dexamethasone (n= 2 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of dexamethasone administered was 40 mg per day, and the dosing schedule was determined by the treating investigator.

NHL subjects were permitted to receive rituximab and/or dexamethasone and/or vincristine as a chemotherapy regimen.

Investigational medicinal product name	Vincristine (n=2 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 4 or after for those with hematologic malignancies. The maximum dose of vincristine administered was 1.5 mg/m^2 per day; (2 mg max; weekly), and the dosing schedule was determined by the treating investigator.

NHL subjects were permitted to receive rituximab and/or dexamethasone and/or vincristine as a chemotherapy regimen.

Arm title	Neuroblastoma (NBL)

Arm description:

Participants with neuroblastoma (NBL)

Arm type	Experimental
Investigational medicinal product name	Venetoclax (n=36 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersible tablet, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects with solid tumors enrolled in Part 1 (Dose Determination) were administered venetoclax orally QD, continuously. Those with solid tumors enrolled in the Part 1 Escalation/De-escalation portion received venetoclax orally QD, continuously or intermittently based on BOIN design and occurrence of DLTs. Results from Part 1 were used to determine venetoclax dosing/regimen for Part 2. Subjects who were < 2 years of age were dosed based on age and those who were 2 years and older were dosed based on weight.

400 mg adult-equivalent target dose: from 2.5 mg Day 1/5 mg Day 2+ for subjects <1 month old to a max of 200 mg Day 1/400 mg Day 2+ for subjects ≥45 kg

600 mg adult-equivalent target dose: from 5 mg Day 1/7.5 mg Day 2+ for subjects <1 month old to a max of 400 mg Day 1/600 mg on Day 2+ for subjects ≥45 kg

800 mg adult-equivalent target dose: from 5 mg Day 1/10 mg Day 2+ for subjects <1 month old to a max of 400 mg Day 1/ 800 mg on Day 2+ for subjects ≥45 kg

Investigational medicinal product name	Cyclophosphamide (n=35 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection

Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 3 or after for those with neuroblastoma or solid tumors. The maximum dose of cyclophosphamide administered was 250 mg/m^2 per day (maximum 5 days every 21 days), and the dosing schedule was determined by the treating investigator.

NBL subjects were permitted to receive cyclophosphamide and topotecan as a chemotherapy regimen.

Investigational medicinal product name	Topotecan (n=35 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate and solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 3 or after for those with neuroblastoma or solid tumors. The maximum dose of topotecan administered was 0.75 mg/m^2 per day (maximum 5 days every 21 days), and the dosing schedule was determined by the treating investigator.

NBL subjects were permitted to receive cyclophosphamide and topotecan as a chemotherapy regimen.

Arm title	Other Tumors

Arm description:

Participants with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse were included in the Other Tumors group. Exception: those with TCF3-HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the Other Tumors group included Secondary Myelodysplastic Syndrome, Myeloid MPAL, Secondary AML, Secondary ALL with TCF3/HLF Fusion, and Mixed Phenotype Acute Leukemia (T/Myeloid).

Arm type	Experimental
Investigational medicinal product name	Venetoclax (n=11 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersible tablet, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Venetoclax was administered orally QD, continuously, in subjects with hematologic malignancies. Subjects who were < 2 years of age were dosed based on age and those who were 2 years and older were dosed based on weight. Subjects with liquid tumors (ALL, AML, NHL) were ramped up over 3 days as follows to achieve 800 mg adult-equivalent target dose:

Newborn to < 1 month (2.5 mg Day 1, 5 mg Day 2, and 10 mg Day 3+)
1 month to < 3 months (5 mg Day 1, 10 mg Day 2, and 25 mg Day 3+)
3 months to < 6 months (10 mg Day 1, 25 mg Day 2, and 50 mg Day 3+)
6 months to < 1 year (25 mg Day 1, 50 mg Day 2, and 100 mg Day 3+)
1 year to < 2 years (40 mg Day 1, 80 mg Day 2, and 150 mg Day 3+)

10 kg to < 20 kg (50 mg Day 1, 120 mg Day 2, and 250 mg Day 3+)
20 kg to < 30 kg (80 mg Day 1, 170 mg Day 2, and 350 mg Day 3+)
30 kg to < 45 kg (120 mg Day 1, 250 mg Day 2, and 500 mg Day 3+)
≥ 45 kg (200 mg Day 1, 400 mg Day 2, and 800 mg Day 3+)

Arm title	Solid Tumors

Arm description:

The Solid Tumors group included participants with solid tumors other than neuroblastoma (except for 2 neuroblastoma participants who had received alternative chemotherapy regimens) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse. The types of primary cancer for the Solid Tumors group included Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing’s Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.

Arm type	Experimental

Investigational medicinal product name	Venetoclax (n=23 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersible tablet, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects with solid tumors enrolled in Part 1 (Dose Determination) were administered venetoclax orally QD, continuously. Those with solid tumors enrolled in the Part 1 Escalation/De-escalation portion received venetoclax orally QD, continuously or intermittently based on BOIN design and occurrence of DLTs. Results from Part 1 were used to determine venetoclax dosing/regimen for Part 2. Subjects who were < 2 years of age were dosed based on age and those who were 2 years and older were dosed based on weight.

400 mg adult-equivalent target dose: from 2.5 mg Day 1/5 mg Day 2+ for subjects <1 month old to a max of 200 mg Day 1/400 mg Day 2+ for subjects ≥45 kg

600 mg adult-equivalent target dose: from 5 mg Day 1/7.5 mg Day 2+ for subjects <1 month old to a max of 400 mg Day 1/600 mg on Day 2+ for subjects ≥45 kg

800 mg adult-equivalent target dose: from 5 mg Day 1/10 mg Day 2+ for subjects <1 month old to a max of 400 mg Day 1/ 800 mg on Day 2+ for subjects ≥45 kg

Investigational medicinal product name	Cyclophosphamide (n=16 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 3 or after for those with neuroblastoma or solid tumors. The maximum dose of cyclophosphamide administered was 250 mg/m^2 per day (maximum 5 days every 21 days), and the dosing schedule was determined by the treating investigator.

Subjects in the Solid Tumors group were permitted to receive cyclophosphamide and/or topotecan as a chemotherapy regimen.

Investigational medicinal product name	Topotecan (n=19 subjects)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate and solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Chemotherapy was added to venetoclax beginning on Day 3 or after for those with neuroblastoma or solid tumors. The maximum dose of topotecan administered was 0.75 mg/m^2 per day (maximum 5 days every 21 days), and the dosing schedule was determined by the treating investigator.

Subjects in the Solid Tumors group were permitted to receive cyclophosphamide and/or topotecan as a chemotherapy regimen.

Number of subjects in period 1	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)
Started	31	37	2
Completed	0	1	0
Not completed	31	36	2
Physician decision	3	5	-
Adverse event, non-fatal	5	1	-
Death	1	-	-

Other, not specified	3	-	-
Progressive disease	9	25	1
Withdrew consent	2	1	-
Transplant	8	4	1

Number of subjects in period 1	Neuroblastoma (NBL)	Other Tumors	Solid Tumors
Started	36	11	23
Completed	2	0	1
Not completed	34	11	22
Physician decision	8	2	2
Adverse event, non-fatal	2	-	1
Death	2	-	1
Other, not specified	3	-	1
Progressive disease	18	6	17
Withdrew consent	1	-	-
Transplant	-	3	-

Baseline characteristics

Reporting groups	
Reporting group title	Acute Lymphoblastic Leukemia (ALL)
Reporting group description:	
Participants with acute lymphoblastic leukemia (ALL)	
Reporting group title	Acute Myeloid Leukemia (AML)
Reporting group description:	
Participants with acute myeloid leukemia (AML)	
Reporting group title	Non-Hodgkin Lymphoma (NHL)
Reporting group description:	
Participants with non-Hodgkin lymphoma (NHL)	
Reporting group title	Neuroblastoma (NBL)
Reporting group description:	
Participants with neuroblastoma (NBL)	
Reporting group title	Other Tumors
Reporting group description:	
Participants with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse were included in the Other Tumors group. Exception: those with TCF3-HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the Other Tumors group included Secondary Myelodysplastic Syndrome, Myeloid MPAL, Secondary AML, Secondary ALL with TCF3/HLF Fusion, and Mixed Phenotype Acute Leukemia (T/Myeloid).	
Reporting group title	Solid Tumors
Reporting group description:	
The Solid Tumors group included participants with solid tumors other than neuroblastoma (except for 2 neuroblastoma participants who had received alternative chemotherapy regimens) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse. The types of primary cancer for the Solid Tumors group included Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing's Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.	

Reporting group values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)
Number of subjects	31	37	2
Age categorical Units: Subjects			
Age continuous Units: years			
median	9.0	6.0	12.0
full range (min-max)	0 to 25	0 to 17	3 to 21
Gender categorical Units: Subjects			
Female	15	19	2
Male	16	18	0

Reporting group values	Neuroblastoma (NBL)	Other Tumors	Solid Tumors
Number of subjects	36	11	23

Age categorical Units: Subjects			

Age continuous Units: years			
median	8.0	10.0	16.0
full range (min-max)	1 to 17	5 to 19	3 to 24
Gender categorical Units: Subjects			
Female	14	5	9
Male	22	6	14

Reporting group values	Total		
Number of subjects	140		
Age categorical Units: Subjects			

Age continuous Units: years			
median			
full range (min-max)	-		
Gender categorical Units: Subjects			
Female	64		
Male	76		

End points reporting groups

Reporting group title	Acute Lymphoblastic Leukemia (ALL)
Reporting group description:	
Participants with acute lymphoblastic leukemia (ALL)	
Reporting group title	Acute Myeloid Leukemia (AML)
Reporting group description:	
Participants with acute myeloid leukemia (AML)	
Reporting group title	Non-Hodgkin Lymphoma (NHL)
Reporting group description:	
Participants with non-Hodgkin lymphoma (NHL)	
Reporting group title	Neuroblastoma (NBL)
Reporting group description:	
Participants with neuroblastoma (NBL)	
Reporting group title	Other Tumors
Reporting group description:	
Participants with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse were included in the Other Tumors group. Exception: those with TCF3-HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the Other Tumors group included Secondary Myelodysplastic Syndrome, Myeloid MPAL, Secondary AML, Secondary ALL with TCF3/HLF Fusion, and Mixed Phenotype Acute Leukemia (T/Myeloid).	
Reporting group title	Solid Tumors
Reporting group description:	
The Solid Tumors group included participants with solid tumors other than neuroblastoma (except for 2 neuroblastoma participants who had received alternative chemotherapy regimens) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse. The types of primary cancer for the Solid Tumors group included Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing’s Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.	
Subject analysis set title	400 mg venetoclax (pharmacokinetic sampling)
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects who were treated with 400 mg venetoclax with viable pharmacokinetic data at Week 2, Day 8	
Subject analysis set title	800 mg venetoclax (pharmacokinetic sampling)
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects who were treated with 800 mg venetoclax with viable pharmacokinetic data at Week 2, Day 8	
Subject analysis set title	Part 1 AML MRD analysis
Subject analysis set type	Full analysis
Subject analysis set description:	
Part 1 participants with acute myeloid leukemia (AML)	
Subject analysis set title	Part 2 AML MRD analysis
Subject analysis set type	Full analysis
Subject analysis set description:	
Part 2 participants with acute myeloid leukemia (AML)	
Subject analysis set title	Part 1 ALL MRD analysis
Subject analysis set type	Full analysis
Subject analysis set description:	
Part 1 participants with acute lymphoblastic leukemia (ALL)	

Subject analysis set title	Part 2 ALL MRD analysis
Subject analysis set type	Full analysis

Subject analysis set description:

Part 2 participants with acute lymphoblastic leukemia (ALL)

Primary: Number of Participants With Adverse Events

End point title	Number of Participants With Adverse Events[1]

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product which does not necessarily have a causal relationship with this treatment. The investigator assesses the relationship of each event to the use of study drug. A serious adverse event (SAE) is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the participant and may require medical or surgical intervention to prevent any of the outcomes listed above. Treatment-emergent adverse events/treatment-emergent serious adverse events (TEAEs/TESAEs) are defined as any event that began or worsened in severity on or after the first dose of study drug.

End point type	Primary

End point timeframe:

From the first dose of study drug to 30 days after last dose, up to 170, 312, 111, 385, 299, and 1168 days for the ALL, AML, NHL, NBL, other tumors, and solid tumors groups, respectively

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

End point values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)	Neuroblastoma (NBL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[2]	37[3]	2[4]	36[5]
Units: number of participants				
Any TEAE	31	37	2	36
TESAE	24	28	1	34

Notes:

[2] - Participants who received at least one dose of study drug

[3] - Participants who received at least one dose of study drug

[4] - Participants who received at least one dose of study drug

[5] - Participants who received at least one dose of study drug

End point values	Other Tumors	Solid Tumors		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11[6]	23[7]		
Units: number of participants				
Any TEAE	11	23		
TESAE	5	18		

Notes:

[6] - Participants who received at least one dose of study drug

[7] - Participants who received at least one dose of study drug

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Participants With Dose Limiting Toxicities (DLT) of Venetoclax Monotherapy

End point title	Part 1: Number of Participants With Dose Limiting Toxicities (DLT) of Venetoclax Monotherapy[8]

End point description:

DLT criteria for ALL/AML:
●Any Grade 5 toxicity
●Grade 4 neutropenia or thrombocytopenia lasting ≥42 days from start of venetoclax administration in absence of evidence of active leukemia
●Any Grade ≥3 non-hematologic toxicity not clearly resulting from the underlying leukemia (with exceptions noted in Section 6.1.8.1 of study protocol)

DLT criteria for NHL/NBL/other solid tumors:
●Any Grade 5 toxicity
●Any Grade 3 or 4 non-hematologic adverse event not clearly related to the underlying tumor (with exceptions noted in Section 6.1.8.1 of the study protocol)

DLT criteria for subjects with adequate bone marrow function at study entry:
●Any Grade 5 hematologic toxicity
●Grade 4 febrile neutropenia
●Grade 4 anemia
●Neutropenia or thrombocytopenia resulting in a delay of > 14 days in meeting criteria (ANC ≥1000/mm3 and platelets ≥75,000/µL) to start a subsequent cycle in the absence of disease in the bone marrow

End point type	Primary

End point timeframe:

During the first 21 days of venetoclax monotherapy in Part 1 (Dose Determination) or during Cycle 1 of combination therapy (venetoclax plus chemotherapy) in Part 1 (Dose Escalation/De-Escalation)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

End point values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)	Neuroblastoma (NBL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[9]	37[10]	2[11]	36[12]
Units: number of participants	2	1	1	4

Notes:

[9] - Participants who received at least one dose of study drug

[10] - Participants who received at least one dose of study drug

[11] - Participants who received at least one dose of study drug

[12] - Participants who received at least one dose of study drug

End point values	Other Tumors	Solid Tumors		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11[13]	23[14]		
Units: number of participants	1	3		

Notes:

[13] - Participants who received at least one dose of study drug

[14] - Participants who received at least one dose of study drug

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Maximum Observed Plasma Concentration (Cmax) of Venetoclax (Week 2, Day 8) of Venetoclax (Week 2, Day 8)

End point title	Part 1: Maximum Observed Plasma Concentration (Cmax) of Venetoclax (Week 2, Day 8) of Venetoclax (Week 2, Day 8)[15]

End point description:

Cmax is the highest concentration that a drug achieves in the blood after administration in a dosing interval.

End point type	Primary

End point timeframe:

0 hrs pre-dose and 2, 4, 6, and 8 hours post-dose at Week 2, Day 8

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

End point values	400 mg venetoclax (pharmacokinetic sampling)	800 mg venetoclax (pharmacokinetic sampling)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31[16]	102[17]		
Units: µg/mL				
arithmetic mean (standard deviation)	1.91 (± 1.38)	2.28 (± 1.66)		

Notes:

[16] - Participants who received at least one dose of study drug with pharmacokinetic data

[17] - Participants who received at least one dose of study drug with pharmacokinetic data

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Time to Maximum Observed Plasma Concentration (Tmax) of Venetoclax (Week 2, Day 8)

End point title	Part 1: Time to Maximum Observed Plasma Concentration (Tmax) of Venetoclax (Week 2, Day 8)[18]

End point description:

Tmax is the the time at which the maximum plasma concentration (Cmax) is observed.

End point type	Primary

End point timeframe:

0 hrs pre-dose and 2, 4, 6, and 8 hours post-dose at Week 2, Day 8

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

End point values	400 mg venetoclax (pharmacokinetic sampling)	800 mg venetoclax (pharmacokinetic sampling)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31[19]	102[20]		
Units: hours				
median (full range (min-max))	5.95 (2.25 to 8.05)	4.37 (0 to 8.58)		

Notes:

[19] - Participants who received at least one dose of study drug with pharmacokinetic data

[20] - Participants who received at least one dose of study drug with pharmacokinetic data

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Area Under the Plasma Concentration-Time Curve Over Time From 0 to 24 Hours (AUC0-24) of Venetoclax (Week 2, Day 8)

End point title	Part 1: Area Under the Plasma Concentration-Time Curve Over Time From 0 to 24 Hours (AUC0-24) of Venetoclax (Week 2, Day 8)[21]

End point description:

AUC is a measure of how long and how much drug is present in the body after dosing.

End point type	Primary

End point timeframe:

0 hrs pre-dose and 2, 4, 6, 8, and 24 hours post-dose at Week 2, Day 8

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

End point values	400 mg venetoclax (pharmacokinetic sampling)	800 mg venetoclax (pharmacokinetic sampling)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31[22]	100[23]		
Units: µg•h/mL				
arithmetic mean (standard deviation)	27.5 (± 24.4)	31.9 (± 25.4)		

Notes:

[22] - Participants who received at least one dose of study drug with pharmacokinetic data

[23] - Participants who received at least one dose of study drug with pharmacokinetic data

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Apparent clearance (CL/F) of venetoclax (Week 2, Day 8)

End point title	Part 1: Apparent clearance (CL/F) of venetoclax (Week 2, Day 8)[24]

End point description:

Clearance is a quantitative measure of the rate at which a drug substance is removed from the body.

End point type	Primary

End point timeframe:

0 hrs pre-dose and 2, 4, 6, and 8 hours post-dose at Week 2, Day 8

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive data are summarized for this end point per protocol.

End point values	400 mg venetoclax (pharmacokinetic sampling)	800 mg venetoclax (pharmacokinetic sampling)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31[25]	100[26]		
Units: L/hour				
arithmetic mean (standard deviation)	25.2 (± 17.9)	44.1 (± 37.3)		

Notes:

[25] - Participants who received at least one dose of study drug with pharmacokinetic data

[26] - Participants who received at least one dose of study drug with pharmacokinetic data

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate

End point title	Objective Response Rate[27]

End point description:

Objective response rate (ORR) is defined as the percentage of participants who achieved a complete response (CR), complete response with incomplete marrow recovery (CRi), complete response without platelet recovery (CRp) or partial response (PR) as best response for participants with ALL or AML; CR or PR as best response for participants with NHL and solid tumors; and CR or PR or minor response (MR) as best response for participants with NBL. Participants who did not achieve an objective response per the above criteria, including those with incomplete or missing data, were considered to be non-responders in the calculation of objective response rate.

End point type	Secondary

End point timeframe:

Response was assessed at each post-baseline visit; overall median time on follow-up was 946 days

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: For the 11 subjects with other tumors in the exploratory cohort, which were included in the Other Tumor analysis group, no efficacy analysis was performed due to the many different tumor types enrolled.

End point values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)	Neuroblastoma (NBL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[28]	37[29]	2[30]	36[31]
Units: percentage of participants				
number (confidence interval 95%)	41.9 (24.5 to 60.9)	24.3 (11.8 to 41.2)	50.0 (1.3 to 98.7)	30.6 (16.3 to 48.1)

Notes:

[28] - Participants who received at least one dose of study drug

[29] - Participants who received at least one dose of study drug

[30] - Participants who received at least one dose of study drug

[31] - Participants who received at least one dose of study drug

End point values	Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	23[32]			

Units: percentage of participants				
number (confidence interval 95%)	21.7 (7.5 to 43.7)			

Notes:

[32] - Participants who received at least one dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response (CR) Rate

End point title	Complete Response (CR) Rate[33]

End point description:

Complete response rate (CRR) is defined as the percentage of participants who achieved a complete response (CR), complete response with incomplete marrow recovery (CRi), or complete response without platelet recovery (CRp) as best response for ALL and AML, and the percentage of participants who achieved a CR as best response for NHL, neuroblastoma, and solid tumors. Participants who did not achieve any component of CR, including those with incomplete or missing data, were considered as non-responders in the calculation of CR rate.

End point type	Secondary

End point timeframe:

Response was assessed at each post-baseline visit; overall median time on follow-up was 946 days

Notes:

[33] - 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: For the 11 subjects with other tumors in the exploratory cohort, which were included in the Other Tumor analysis group, no efficacy analysis was performed due to the many different tumor types enrolled.

End point values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)	Neuroblastoma (NBL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[34]	37[35]	2[36]	36[37]
Units: percentage of participants				
number (confidence interval 95%)	41.9 (24.5 to 60.9)	16.2 (6.2 to 32.0)	0 (0.0 to 84.2)	22.2 (10.1 to 39.2)

Notes:

[34] - Participants who received at least one dose of study drug

[35] - Participants who received at least one dose of study drug

[36] - Participants who received at least one dose of study drug

[37] - Participants who received at least one dose of study drug

End point values	Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	23[38]			
Units: percentage of participants				
number (confidence interval 95%)	4.3 (0.1 to 21.9)			

Notes:

[38] - Participants who received at least one dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Partial Response Rate

End point title	Partial Response Rate[39]

End point description:

Partial response rate (PRR) is defined as the percentage of participants who achieved a PR as best response. Participants who did not achieve a PR as best response, including those with incomplete or missing data, were considered as non-responders in the calculation of PR rate.

End point type	Secondary

End point timeframe:

Response was assessed at each post-baseline visit; overall median time on follow-up was 946 days

Notes:

[39] - 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: For the 11 subjects with other tumors in the exploratory cohort, which were included in the Other Tumor analysis group, no efficacy analysis was performed due to the many different tumor types enrolled.

End point values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)	Neuroblastoma (NBL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[40]	37[41]	2[42]	36[43]
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 11.2)	8.1 (1.7 to 21.9)	50.0 (1.3 to 98.7)	8.3 (1.8 to 22.5)

Notes:

[40] - Participants who received at least one dose of study drug

[41] - Participants who received at least one dose of study drug

[42] - Participants who received at least one dose of study drug

[43] - Participants who received at least one dose of study drug

End point values	Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	23[44]			
Units: percentage of participants				
number (confidence interval 95%)	17.4 (5.0 to 38.8)			

Notes:

[44] - Participants who received at least one dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

End point title	Progression-free Survival (PFS)[45]

End point description:

Progression-free survival (PFS) is defined as the number of days from the date of the first dose of study drug to the date of earliest disease progression or death. All events of disease progression were included regardless of whether the event occurred while the participant was taking study drug or had previously discontinued the study drug. If the participant had not experienced disease progression or death, their data were censored at the date of the last disease assessment. Data for those without any disease assessments performed after the first dose of study drug were censored at the date of the first dose of study drug plus 1 day. PFS was analyzed by Kaplan-Meier methodology.

In the table below, 999 and 99999 indicate not calculable/estimable due to low number of participants with events.

End point type	Secondary

End point timeframe:

Overall median time on follow-up was 946 days

Notes:

[45] - 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: For the 11 subjects with other tumors in the exploratory cohort, which were included in the Other Tumor analysis group, no efficacy analysis was performed due to the many different tumor types enrolled.

End point values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)	Neuroblastoma (NBL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[46]	37[47]	2[48]	36[49]
Units: days				
median (confidence interval 95%)	28.0 (22.0 to 95.0)	42.0 (31.0 to 76.0)	999 (14.0 to 99999)	114.0 (58.0 to 224.0)

Notes:

[46] - Participants who received at least one dose of study drug

[47] - Participants who received at least one dose of study drug

[48] - Participants who received at least one dose of study drug

[49] - Participants who received at least one dose of study drug

End point values	Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	23[50]			
Units: days				
median (confidence interval 95%)	88.0 (49.0 to 245.0)			

Notes:

[50] - Participants who received at least one dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival[51]

End point description:

Overall survival (OS) is defined as the number of days from the date of the first dose of study drug to the date of death. Data from participants that were alive at the time of analysis were censored at the

date of last study visit or the last known date the participant was alive, whichever was later. OS was analyzed by Kaplan-Meier methodology.

In the table below, 999 and 99999 indicate not calculable/estimable due to low number of participants with events.

End point type	Secondary

End point timeframe:

Overall median time on follow-up was 946 days

Notes:

[51] - 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: For the 11 subjects with other tumors in the exploratory cohort, which were included in the Other Tumor analysis group, no efficacy analysis was performed due to the many different tumor types enrolled.

End point values	Acute Lymphoblastic Leukemia (ALL)	Acute Myeloid Leukemia (AML)	Non-Hodgkin Lymphoma (NHL)	Neuroblastoma (NBL)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[52]	37[53]	2[54]	36[55]
Units: days				
median (confidence interval 95%)	118.0 (75.0 to 290.0)	110.0 (76.0 to 216.0)	999 (31.0 to 99999)	431.0 (195.0 to 721.0)

Notes:

[52] - Participants who received at least one dose of study drug

[53] - Participants who received at least one dose of study drug

[54] - Participants who received at least one dose of study drug

[55] - Participants who received at least one dose of study drug

End point values	Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	23[56]			
Units: days				
median (confidence interval 95%)	180.0 (107.0 to 714.0)			

Notes:

[56] - Participants who received at least one dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Minimal Residual Disease (MRD) negativity rate

End point title	Minimal Residual Disease (MRD) negativity rate

End point description:

MRD negativity rate is defined as the percentage of participants who achieved MRD negativity. MRD status that was collected after start of post study-treatment cancer therapy, if applicable, was included in the analyses. Participants who did not achieve MRD negativity, including those without MRD assessment, were considered to be non-responders in the calculation of MRD negativity status.

End point type	Secondary

End point timeframe:

Overall median time on follow-up was 946 days

End point values	Part 1 AML MRD analysis	Part 2 AML MRD analysis	Part 1 ALL MRD analysis	Part 2 ALL MRD analysis
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10[57]	27[58]	5[59]	26[60]
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 30.8)	7.4 (0.9 to 24.3)	40.0 (5.3 to 85.3)	26.9 (11.6 to 47.8)

Notes:

[57] - Participants with AML who received at least one dose of study drug with available data

[58] - Participants with AML who received at least one dose of study drug with available data

[59] - Participants with ALL who received at least one dose of study drug with available data

[60] - Participants with ALL who received at least one dose of study drug with available data

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events and serious adverse events collected from 1st dose of study drug to 30 days after last dose, up to 170, 312, 111, 385, 299, and 1168 days for the ALL, AML, NHL, NBL, other tumors, and solid tumors groups, respectively.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	ALL venetoclax 800 mg

Reporting group description:

Participants with acute lymphoblastic leukemia (ALL) who received 800 mg of venetoclax

Reporting group title	AML venetoclax 800 mg

Reporting group description:

Participants with with acute myeloid leukemia (AML) who received 800 mg of venetoclax

Reporting group title	NHL venetoclax 800 mg

Reporting group description:

Participants with non-Hodgkin lymphoma (NHL) who received 800 mg of venetoclax

Reporting group title	NBL venetoclax 800 mg

Reporting group description:

Participants with neuroblastoma (NBL) who received 800 mg of venetoclax

Reporting group title	Solid Tumors Part 2 Expansion

Reporting group description:

Participants with solid tumors other than neuroblastoma (with the exception of 2 participants who had received alternative chemotherapies) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse treated with venetoclax during Part 2 of the study. Exception: those with TCF3- HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the solid tumors group include Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing’s Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.

Reporting group title	Solid tumors venetoclax 400 mg

Reporting group description:

Participants with solid tumors other than neuroblastoma (with the exception of 2 participants who had received alternative chemotherapies) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse treated with 400 mg of venetoclax. Exception: those with TCF3- HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the solid tumors group include Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing’s Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.

Reporting group title	Solid tumors venetoclax 400 mg intermittent

Reporting group description:

Participants with solid tumors other than neuroblastoma (with the exception of 2 participants who had received alternative chemotherapies) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse treated intermittently with 400 mg of venetoclax. Exception: those with TCF3- HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the solid tumors group include Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing’s Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.

Reporting group title	Solid tumors venetoclax 800 mg intermittent

Reporting group description:

Participants with solid tumors other than neuroblastoma (with the exception of 2 participants who had received alternative chemotherapies) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse treated intermittently with 800 mg of venetoclax. Exception: those with TCF3- HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the solid tumors group include Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing's Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.

Reporting group title	Solid tumors Part 1 Dose Determination

Reporting group description:

Participants with solid tumors other than neuroblastoma (with the exception of 2 participants who had received alternative chemotherapies) with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse treated with venetoclax during Part 1 of the study. Exception: those with TCF3- HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the solid tumors group include Wilms Tumor, Gastrointestinal Stromal Tumor, Synovial Sarcoma, Alveolar Rhabdomyosarcoma, Biliary Tract Rhabdomyosarcoma, Embryonal Rhabdomyosarcoma, Ewing's Sarcoma, Desmoplastic Small Round Cell Tumor, NRSTS (BCOR), and Evans Tumor.

Reporting group title	Other tumors venetoclax 800 mg

Reporting group description:

Participants with evidence of BCL-2 expression determined locally in either archived tumor tissue or tumor tissue available at relapse who were treated with 800 mg of venetoclax. Exception: those with TCF3- HLF ALL enrolled in this group were not required to have evidence of BCL-2 expression. The types of primary cancer for the other tumors group include Myelodysplastic Syndrome, Myeloid MPAL, AML, ALL with TCF3/HLF Fusion, and Mixed Phenotype Acute Leukemia (T/Myeloid).

Serious adverse events	ALL venetoclax 800 mg	AML venetoclax 800 mg	NHL venetoclax 800 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 31 (77.42%)	28 / 37 (75.68%)	1 / 2 (50.00%)
number of deaths (all causes)	23	31	1
number of deaths resulting from adverse events	6	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEOPLASM			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
LEUKAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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

TUMOUR PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
THROMBOSIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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			
DISEASE PROGRESSION			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			

subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
FACIAL PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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			
HYPERSENSITIVITY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
EPISTAXIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

LUNG DISORDER			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
PULMONARY OEDEMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
BLOOD BILIRUBIN INCREASED			

subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEMICAL PERITONITIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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			
CARDIAC FAILURE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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			
NEURALGIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
NEUROTOXICITY			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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			
FEBRILE NEUTROPENIA			
subjects affected / exposed	13 / 31 (41.94%)	18 / 37 (48.65%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	28 / 34	17 / 38	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
FEBRILE BONE MARROW APLASIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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			
ABDOMINAL PAIN			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
ASCITES			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DIARRHOEA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
PROCTALGIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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			
VENOOCCLUSIVE LIVER DISEASE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
HEPATOSPLENOMEGALY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
Skin and subcutaneous tissue disorders			

ACUTE FEBRILE NEUTROPHILIC DERMATOSIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPHILIC PANNICULITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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 ULCER			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
HAEMATURIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYSTITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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			
ARTHRALGIA			

subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
BACK PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 JAW			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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			
ASPERGILLUS INFECTION			

subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
APPENDICITIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS LIMB			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
ATYPICAL MYCOBACTERIAL PNEUMONIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
BACTERAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (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
BRONCHOPULMONARY ASPERGILLOSIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (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
CLOSTRIDIAL INFECTION			

subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
CORYNEBACTERIUM INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
ENTEROCOCCAL INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
ENTEROCOCCAL SEPSIS			

subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
ENTEROCOLITIS INFECTIOUS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
ESCHERICHIA INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
ESCHERICHIA SEPSIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
FUNGAL INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
FOLLICULITIS			

subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
NASOPHARYNGITIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCORMYCOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
METAPNEUMOVIRUS INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
NOROVIRUS INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
OTITIS MEDIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARAINFLUENZAE VIRUS INFECTION			

subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA FUNGAL			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	3 / 31 (9.68%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	3 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
PSEUDOMONAL BACTERAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
SEPSIS			
subjects affected / exposed	5 / 31 (16.13%)	2 / 37 (5.41%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	2 / 5	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SERRATIA SEPSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
STOMA SITE INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
SOFT TISSUE INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
VULVITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
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 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
HYPOKALAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (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
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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
METABOLIC ACIDOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (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

Serious adverse events	NBL venetoclax 800 mg	Solid Tumors Part 2 Expansion	Solid tumors venetoclax 400 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	34 / 36 (94.44%)	7 / 8 (87.50%)	1 / 2 (50.00%)
number of deaths (all causes)	20	5	1
number of deaths resulting from adverse events	1	1	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEOPLASM			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	4 / 36 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	3 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
HYPERTENSION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOSIS			

subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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			
DISEASE PROGRESSION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
PYREXIA			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	1 / 36 (2.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
FACIAL PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPISTAXIS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
HYPOXIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 OEDEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 BILIRUBIN INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (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
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLATELET COUNT DECREASED			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			

subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
CHEMICAL PERITONITIS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (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
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
NEURALGIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROTOXICITY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 CORD COMPRESSION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
SYNCOPE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
FEBRILE NEUTROPENIA			
subjects affected / exposed	25 / 36 (69.44%)	5 / 8 (62.50%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	55 / 61	8 / 12	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA			
subjects affected / exposed	4 / 36 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	5 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 BONE MARROW APLASIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
NEUTROPENIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

ABDOMINAL PAIN			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (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
COLITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 36 (2.78%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
Hepatobiliary disorders			

VENOOCCLUSIVE LIVER DISEASE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOSPLENOMEGALY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
ACUTE FEBRILE NEUTROPHILIC DERMATOSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPHILIC PANNICULITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 ULCER			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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

CYSTITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (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
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 JAW			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
ABSCESS LIMB			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 MYCOBACTERIAL PNEUMONIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BRONCHOPULMONARY ASPERGILLOSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIAL INFECTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM COLITIS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORYNEBACTERIUM INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL BACTERAEMIA			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL SEPSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 INFECTIOUS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 SEPSIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (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
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FUNGAL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOLLICULITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
MUCORMYCOSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METAPNEUMOVIRUS INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NOROVIRUS INFECTION			

subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
OTITIS MEDIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
PARAINFLUENZAE VIRUS INFECTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA FUNGAL			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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 BACTERAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			

subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
SERRATIA SEPSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 BACTERAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFECTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
VULVITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
VARICELLA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (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
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METABOLIC ACIDOSIS			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	Solid tumors venetoclax 400 mg intermittent	Solid tumors venetoclax 800 mg intermittent	Solid tumors Part 1 Dose Determination
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 5 (60.00%)	3 / 4 (75.00%)
number of deaths (all causes)	3	5	2
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEOPLASM			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (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
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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
Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
DISEASE PROGRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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
Immune system disorders			

HYPERSENSITIVITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOKINE RELEASE SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPISTAXIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (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
PNEUMOTHORAX			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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
PULMONARY HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 BILIRUBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLATELET COUNT DECREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEMICAL PERITONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
NEURALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROTOXICITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 CORD COMPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
FEBRILE NEUTROPENIA			
subjects affected / exposed	4 / 4 (100.00%)	0 / 5 (0.00%)	3 / 4 (75.00%)
occurrences causally related to treatment / all	6 / 6	0 / 0	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 BONE MARROW APLASIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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
COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
VENOOCCLUSIVE LIVER DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOSPLENOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
ACUTE FEBRILE NEUTROPHILIC DERMATOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPHILIC PANNICULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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
CYSTITIS HAEMORRHAGIC			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (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
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
ARTHRALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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
BONE PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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 JAW			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (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			
ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS LIMB			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 MYCOBACTERIAL PNEUMONIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOPULMONARY ASPERGILLOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORYNEBACTERIUM INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 INFECTIOUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 SEPSIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FUNGAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOLLICULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUCORMYCOSIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METAPNEUMOVIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NOROVIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OTITIS MEDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARAINFLUENZAE VIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 FUNGAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 BACTERAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (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
SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SERRATIA SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 BACTERAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VULVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICELLA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOCALCAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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	Other tumors venetoclax 800 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 11 (45.45%)		
number of deaths (all causes)	7		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEOPLASM			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
LEUKAEMIA			

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
TUMOUR PAIN				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
HYPOTENSION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPERTENSION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
THROMBOPHLEBITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
THROMBOSIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
DISEASE PROGRESSION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PYREXIA				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

MULTIPLE ORGAN DYSFUNCTION SYNDROME				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FACIAL PAIN				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
NON-CARDIAC CHEST PAIN				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
HYPERSENSITIVITY				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CYTOKINE RELEASE SYNDROME				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
DYSPNOEA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
EPISTAXIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPOXIA				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
LUNG DISORDER				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMOTHORAX				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PULMONARY HAEMORRHAGE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PULMONARY OEDEMA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
RESPIRATORY FAILURE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
ALANINE AMINOTRANSFERASE INCREASED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

BLOOD BILIRUBIN INCREASED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
NEUTROPHIL COUNT DECREASED				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
INTERNATIONAL NORMALISED RATIO INCREASED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PLATELET COUNT DECREASED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
WHITE BLOOD CELL COUNT DECREASED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
INFUSION RELATED REACTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CHEMICAL PERITONITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
POST PROCEDURAL HAEMORRHAGE				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
NEURALGIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
NEUROTOXICITY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SEIZURE			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SYNCOPE			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
FEBRILE NEUTROPENIA			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences causally related to treatment / all	5 / 7		
deaths causally related to treatment / all	0 / 0		
ANAEMIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
FEBRILE BONE MARROW APLASIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
NEUTROPENIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COLITIS			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

ASCITES				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DIARRHOEA				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
STOMATITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PROCTALGIA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
NAUSEA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VOMITING				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
VENOOCCLUSIVE LIVER DISEASE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPERBILIRUBINAEMIA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HEPATOSPLENOMEGALY				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
ACUTE FEBRILE NEUTROPHILIC DERMATOSIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
NEUTROPHILIC PANNICULITIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SKIN ULCER			
subjects affected / exposed	0 / 11 (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 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HAEMATURIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
CYSTITIS HAEMORRHAGIC			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BACK PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
FLANK PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BONE PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PAIN IN JAW			
subjects affected / exposed	0 / 11 (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 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Infections and infestations			
ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
APPENDICITIS			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
ABSCESS LIMB			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ATYPICAL MYCOBACTERIAL PNEUMONIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BACTERAEMIA			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
BACTERIAL INFECTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BRONCHOPULMONARY ASPERGILLOSIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
CELLULITIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

CLOSTRIDIAL INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CLOSTRIDIUM COLITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CLOSTRIDIUM DIFFICILE COLITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CLOSTRIDIUM DIFFICILE INFECTION				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
CORYNEBACTERIUM INFECTION				
subjects affected / exposed	0 / 11 (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 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ENTEROCOCCAL BACTERAEMIA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ENTEROCOCCAL INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ENTEROCOCCAL SEPSIS				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ENTEROCOLITIS INFECTIOUS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ESCHERICHIA INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ESCHERICHIA SEPSIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
KLEBSIELLA INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
INFLUENZA				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FUNGAL INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FOLLICULITIS				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
NECROTISING FASCIITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
NASOPHARYNGITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MUCORMYCOSIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
METAPNEUMOVIRUS INFECTION				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
MENINGITIS				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
NOROVIRUS INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
OTITIS MEDIA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PARAINFLUENZAE VIRUS INFECTION				

subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA FUNGAL				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PSEUDOMONAL BACTERAEMIA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
RHINOVIRUS INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SEPSIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SEPTIC SHOCK				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SERRATIA SEPSIS				
subjects affected / exposed	0 / 11 (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 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
STOMA SITE INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
STAPHYLOCOCCAL INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
STAPHYLOCOCCAL BACTERAEMIA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SOFT TISSUE INFECTION				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
VULVITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VASCULAR DEVICE INFECTION				
subjects affected / exposed	2 / 11 (18.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
VARICELLA				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
DECREASED APPETITE				

subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
DEHYDRATION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HYPOCALCAEMIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HYPOKALAEMIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 11 (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	ALL venetoclax 800 mg	AML venetoclax 800 mg	NHL venetoclax 800 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 31 (100.00%)	36 / 37 (97.30%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
SKIN PAPILLOMA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
FLUSHING			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	5 / 31 (16.13%)	10 / 37 (27.03%)	0 / 2 (0.00%)
occurrences (all)	6	15	0
HYPERTENSION			
subjects affected / exposed	8 / 31 (25.81%)	8 / 37 (21.62%)	1 / 2 (50.00%)
occurrences (all)	11	10	1
HAEMATOMA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VENOUS HAEMORRHAGE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
CATHETER SITE HAEMORRHAGE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE IRRITATION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

CHEST PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
AXILLARY PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
FACE OEDEMA			
subjects affected / exposed	1 / 31 (3.23%)	2 / 37 (5.41%)	1 / 2 (50.00%)
occurrences (all)	2	2	1
MALAISE			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
LOCALISED OEDEMA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
GAIT DISTURBANCE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	13 / 31 (41.94%)	7 / 37 (18.92%)	0 / 2 (0.00%)
occurrences (all)	15	8	0
MEDICAL DEVICE SITE ERYTHEMA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

PUNCTURE SITE PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	4 / 31 (12.90%)	8 / 37 (21.62%)	0 / 2 (0.00%)
occurrences (all)	5	8	0
OEDEMA PERIPHERAL			
subjects affected / exposed	5 / 31 (16.13%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	6	4	0
OEDEMA			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 31 (0.00%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	7 / 31 (22.58%)	11 / 37 (29.73%)	1 / 2 (50.00%)
occurrences (all)	7	22	2
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	3 / 31 (9.68%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PERINEAL PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OEDEMA GENITAL			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
Respiratory, thoracic and mediastinal disorders			

DYSPNOEA			
subjects affected / exposed	3 / 31 (9.68%)	2 / 37 (5.41%)	1 / 2 (50.00%)
occurrences (all)	5	2	1
COUGH			
subjects affected / exposed	6 / 31 (19.35%)	6 / 37 (16.22%)	0 / 2 (0.00%)
occurrences (all)	9	6	0
ATELECTASIS			
subjects affected / exposed	0 / 31 (0.00%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
RHINORRHOEA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TACHYPNOEA			
subjects affected / exposed	1 / 31 (3.23%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
PLEURAL EFFUSION			
subjects affected / exposed	3 / 31 (9.68%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	3	3	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	4 / 31 (12.90%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	4	1	0
NASAL CONGESTION			
subjects affected / exposed	0 / 31 (0.00%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	5 / 31 (16.13%)	7 / 37 (18.92%)	0 / 2 (0.00%)
occurrences (all)	8	8	0
EPISTAXIS			
subjects affected / exposed	7 / 31 (22.58%)	7 / 37 (18.92%)	0 / 2 (0.00%)
occurrences (all)	7	7	0

Psychiatric disorders			
DEPRESSED MOOD			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
CONFUSIONAL STATE			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	4	2	0
ANXIETY			
subjects affected / exposed	5 / 31 (16.13%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	5	2	0
AGITATION			
subjects affected / exposed	2 / 31 (6.45%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	2	5	0
INITIAL INSOMNIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
IRRITABILITY			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
INSOMNIA			
subjects affected / exposed	2 / 31 (6.45%)	2 / 37 (5.41%)	1 / 2 (50.00%)
occurrences (all)	2	2	1
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
BLOOD CORTICOTROPHIN DECREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	6 / 31 (19.35%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	7	8	0

BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	3 / 31 (9.68%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	5	1	0
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	3 / 31 (9.68%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	13 / 31 (41.94%)	11 / 37 (29.73%)	1 / 2 (50.00%)
occurrences (all)	25	11	1
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	16 / 31 (51.61%)	11 / 37 (29.73%)	1 / 2 (50.00%)
occurrences (all)	27	18	1
BLOOD CREATININE INCREASED			
subjects affected / exposed	2 / 31 (6.45%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	3	6	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	3 / 31 (9.68%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	6	0	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CARDIAC MURMUR			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1

BLOOD FIBRINOGEN DECREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FLUID BALANCE POSITIVE			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	1 / 2 (50.00%)
occurrences (all)	1	1	2
HAEMOGLOBIN INCREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROTHROMBIN TIME PROLONGED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	6 / 31 (19.35%)	6 / 37 (16.22%)	0 / 2 (0.00%)
occurrences (all)	10	6	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	1 / 2 (50.00%)
occurrences (all)	2	2	2
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	4 / 31 (12.90%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	10	9	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
HAPTOGLOBIN DECREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
WHITE BLOOD CELL COUNT DECREASED			

subjects affected / exposed	4 / 31 (12.90%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	7	10	0
WEIGHT INCREASED			
subjects affected / exposed	2 / 31 (6.45%)	8 / 37 (21.62%)	0 / 2 (0.00%)
occurrences (all)	6	14	0
WEIGHT DECREASED			
subjects affected / exposed	2 / 31 (6.45%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	4	5	0
SERUM FERRITIN INCREASED			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ALLERGIC TRANSFUSION REACTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
CONTUSION			
subjects affected / exposed	1 / 31 (3.23%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	1	6	0
FALL			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
PRODUCT USE COMPLAINT			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
STOMA SITE ERYTHEMA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS COMPLICATION			

subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
WOUND SECRETION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
FANCONI SYNDROME			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONGENITAL POIKILODERMA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
BRADYCARDIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PERICARDIAL EFFUSION			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
TACHYCARDIA			
subjects affected / exposed	1 / 31 (3.23%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
SINUS TACHYCARDIA			
subjects affected / exposed	9 / 31 (29.03%)	6 / 37 (16.22%)	0 / 2 (0.00%)
occurrences (all)	11	11	0
SINUS BRADYCARDIA			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	2 / 31 (6.45%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
DYSGEUSIA			

subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	7 / 31 (22.58%)	8 / 37 (21.62%)	0 / 2 (0.00%)
occurrences (all)	7	12	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PARAESTHESIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Blood and lymphatic system disorders			
FEBRILE NEUTROPENIA			
subjects affected / exposed	4 / 31 (12.90%)	3 / 37 (8.11%)	1 / 2 (50.00%)
occurrences (all)	5	3	1
ANAEMIA			
subjects affected / exposed	11 / 31 (35.48%)	10 / 37 (27.03%)	1 / 2 (50.00%)
occurrences (all)	14	12	1

COAGULOPATHY			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERLEUKOCYTOSIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	4 / 31 (12.90%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	8	5	0
SPLENOMEGALY			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
THROMBOCYTOPENIA			
subjects affected / exposed	11 / 31 (35.48%)	8 / 37 (21.62%)	0 / 2 (0.00%)
occurrences (all)	14	10	0
LYMPHOPENIA			
subjects affected / exposed	5 / 31 (16.13%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	9	13	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
LEUKOPENIA			
subjects affected / exposed	7 / 31 (22.58%)	5 / 37 (13.51%)	1 / 2 (50.00%)
occurrences (all)	14	11	2
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	6	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	3 / 31 (9.68%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
PERIORBITAL OEDEMA			

subjects affected / exposed	2 / 31 (6.45%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	2	4	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	11 / 31 (35.48%)	6 / 37 (16.22%)	0 / 2 (0.00%)
occurrences (all)	12	7	0
ABDOMINAL DISTENSION			
subjects affected / exposed	4 / 31 (12.90%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	4	3	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
ANAL INCONTINENCE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
ANAL FISSURE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANAL INFLAMMATION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
DIARRHOEA			
subjects affected / exposed	12 / 31 (38.71%)	17 / 37 (45.95%)	0 / 2 (0.00%)
occurrences (all)	17	21	0
CONSTIPATION			
subjects affected / exposed	8 / 31 (25.81%)	7 / 37 (18.92%)	1 / 2 (50.00%)
occurrences (all)	9	9	1
CHEILITIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

FAECALOMA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
DRY MOUTH			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FOOD POISONING			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
GINGIVAL BLEEDING			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GINGIVAL HYPERTROPHY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
MOUTH ULCERATION			

subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
OESOPHAGITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ODYNOPHAGIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OBSTRUCTION GASTRIC			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	12 / 31 (38.71%)	16 / 37 (43.24%)	1 / 2 (50.00%)
occurrences (all)	16	19	1
ORAL BLOOD BLISTER			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL DISORDER			
subjects affected / exposed	3 / 31 (9.68%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
STOMATITIS			
subjects affected / exposed	3 / 31 (9.68%)	3 / 37 (8.11%)	1 / 2 (50.00%)
occurrences (all)	3	3	1
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
PROCTALGIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
PROCTITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
TOOTH LOSS			

subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
VOMITING			
subjects affected / exposed	14 / 31 (45.16%)	24 / 37 (64.86%)	1 / 2 (50.00%)
occurrences (all)	18	41	1
Hepatobiliary disorders			
HEPATOMEGALY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
HEPATIC FAILURE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEPATIC CYTOLYSIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	3 / 31 (9.68%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
DRY SKIN			
subjects affected / exposed	1 / 31 (3.23%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
ERYTHEMA			
subjects affected / exposed	1 / 31 (3.23%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
URTICARIA			

subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SKIN ULCER			
subjects affected / exposed	1 / 31 (3.23%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	1 / 31 (3.23%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
RASH MACULO-PAPULAR			
subjects affected / exposed	1 / 31 (3.23%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
PETECHIAE			
subjects affected / exposed	5 / 31 (16.13%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	6	0	0
PRURITUS			
subjects affected / exposed	3 / 31 (9.68%)	6 / 37 (16.22%)	1 / 2 (50.00%)
occurrences (all)	5	6	2
PURPURA			
subjects affected / exposed	2 / 31 (6.45%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
RASH			
subjects affected / exposed	3 / 31 (9.68%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
Renal and urinary disorders			
PROTEINURIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

RENAL FAILURE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GLYCOSURIA			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	3 / 31 (9.68%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
CUSHINGOID			
subjects affected / exposed	3 / 31 (9.68%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	6 / 31 (19.35%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	9	2	0
BACK PAIN			
subjects affected / exposed	6 / 31 (19.35%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	8	5	0
MUSCULAR WEAKNESS			
subjects affected / exposed	3 / 31 (9.68%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
GROIN PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
FLANK PAIN			

subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
BONE PAIN			
subjects affected / exposed	0 / 31 (0.00%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
PAIN IN JAW			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PAIN IN EXTREMITY			
subjects affected / exposed	9 / 31 (29.03%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	9	9	0
NECK PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
MYALGIA			
subjects affected / exposed	5 / 31 (16.13%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	6	2	0
MYOSITIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BLASTOCYSTIS INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BACTEROIDES INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

ADENOVIRUS INFECTION			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
CANDIDA INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
ENTEROCOCCAL INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
COVID-19			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CORONAVIRUS INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVITIS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
CLOSTRIDIAL INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ENTEROCOLITIS INFECTIOUS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
GINGIVITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

HERPES SIMPLEX			
subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
NAIL INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
LOWER RESPIRATORY TRACT INFECTION FUNGAL			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	2 / 31 (6.45%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
OTITIS MEDIA ACUTE			
subjects affected / exposed	0 / 31 (0.00%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
RHINITIS			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
RASH PUSTULAR			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA FUNGAL			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA			
subjects affected / exposed	2 / 31 (6.45%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
PHARYNGITIS			

subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VIRAL INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
STREPTOCOCCAL INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	3 / 37 (8.11%)	1 / 2 (50.00%)
occurrences (all)	0	3	1
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 31 (3.23%)	8 / 37 (21.62%)	0 / 2 (0.00%)
occurrences (all)	1	10	0
DEHYDRATION			
subjects affected / exposed	3 / 31 (9.68%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 31 (0.00%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HYPERPHOSPHATAEMIA			

subjects affected / exposed	1 / 31 (3.23%)	1 / 37 (2.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
HYPERNATRAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
HYPERMAGNESAEMIA			
subjects affected / exposed	3 / 31 (9.68%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	3	3	0
HYPERKALAEMIA			
subjects affected / exposed	7 / 31 (22.58%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	9	3	0
HYPERGLYCAEMIA			
subjects affected / exposed	7 / 31 (22.58%)	4 / 37 (10.81%)	0 / 2 (0.00%)
occurrences (all)	9	5	0
HYPERCALCAEMIA			
subjects affected / exposed	2 / 31 (6.45%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	4	3	0
HYPOALBUMINAEMIA			
subjects affected / exposed	7 / 31 (22.58%)	7 / 37 (18.92%)	0 / 2 (0.00%)
occurrences (all)	14	8	0
HYPERVOLAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	3 / 37 (8.11%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
HYPERURICAEMIA			
subjects affected / exposed	3 / 31 (9.68%)	2 / 37 (5.41%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
HYPOCALCAEMIA			
subjects affected / exposed	10 / 31 (32.26%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	18	9	0
HYPOGLYCAEMIA			
subjects affected / exposed	4 / 31 (12.90%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	6	0	0
HYPOKALAEMIA			
subjects affected / exposed	16 / 31 (51.61%)	17 / 37 (45.95%)	0 / 2 (0.00%)
occurrences (all)	32	28	0
HYPOMAGNESAEMIA			

subjects affected / exposed	6 / 31 (19.35%)	5 / 37 (13.51%)	0 / 2 (0.00%)
occurrences (all)	12	11	0
HYPONATRAEMIA			
subjects affected / exposed	9 / 31 (29.03%)	6 / 37 (16.22%)	0 / 2 (0.00%)
occurrences (all)	13	8	0
REFEEDING SYNDROME			
subjects affected / exposed	0 / 31 (0.00%)	0 / 37 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	13 / 31 (41.94%)	7 / 37 (18.92%)	0 / 2 (0.00%)
occurrences (all)	23	8	0

Non-serious adverse events	NBL venetoclax 800 mg	Solid Tumors Part 2 Expansion	Solid tumors venetoclax 400 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 36 (100.00%)	7 / 8 (87.50%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
SKIN PAPILLOMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	5 / 36 (13.89%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
HYPERTENSION			
subjects affected / exposed	4 / 36 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	4	1	0
HAEMATOMA			

subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
VENOUS HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
CATHETER SITE HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE IRRITATION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
CHEST PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
AXILLARY PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
FACE OEDEMA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
MALAISE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LOCALISED OEDEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE BRUISING			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	12 / 36 (33.33%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	19	2	0
MEDICAL DEVICE SITE ERYTHEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PUNCTURE SITE PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	2 / 36 (5.56%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	2	1	1
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
OEDEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	2 / 36 (5.56%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
PYREXIA			
subjects affected / exposed	7 / 36 (19.44%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	8	2	0
Immune system disorders			

DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PERINEAL PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OEDEMA GENITAL			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
COUGH			
subjects affected / exposed	5 / 36 (13.89%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	6	0	0
ATELECTASIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
TACHYPNOEA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			

subjects affected / exposed	2 / 36 (5.56%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
NASAL CONGESTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
EPISTAXIS			
subjects affected / exposed	7 / 36 (19.44%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	9	0	0
Psychiatric disorders			
DEPRESSED MOOD			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
AGITATION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
INITIAL INSOMNIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
IRRITABILITY			
subjects affected / exposed	1 / 36 (2.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
INSOMNIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD CORTICOTROPHIN DECREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	5 / 36 (13.89%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	9	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	7 / 36 (19.44%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	10	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	6 / 36 (16.67%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	8	1	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CORTISOL DECREASED			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CARDIAC MURMUR			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN DECREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FLUID BALANCE POSITIVE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
HAEMOGLOBIN INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROTHROMBIN TIME PROLONGED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	15 / 36 (41.67%)	4 / 8 (50.00%)	1 / 2 (50.00%)
occurrences (all)	28	8	1
NEUTROPHIL COUNT DECREASED			

subjects affected / exposed	17 / 36 (47.22%)	3 / 8 (37.50%)	0 / 2 (0.00%)
occurrences (all)	43	3	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	16 / 36 (44.44%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	35	2	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAPTOGLOBIN DECREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	17 / 36 (47.22%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	37	2	1
WEIGHT INCREASED			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
WEIGHT DECREASED			
subjects affected / exposed	6 / 36 (16.67%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	8	3	0
SERUM FERRITIN INCREASED			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ALLERGIC TRANSFUSION REACTION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
CONTUSION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
FALL			

subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
PRODUCT USE COMPLAINT			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
STOMA SITE ERYTHEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS COMPLICATION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
WOUND SECRETION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
FANCONI SYNDROME			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CONGENITAL POIKILODERMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
BRADYCARDIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
PALPITATIONS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PERICARDIAL EFFUSION			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	4 / 36 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	4 / 36 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	9	2	0
SINUS BRADYCARDIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	2 / 36 (5.56%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	2	1	1
DYSGEUSIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
HEADACHE			
subjects affected / exposed	10 / 36 (27.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	13	2	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	0 / 36 (0.00%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
FEBRILE NEUTROPENIA			
subjects affected / exposed	3 / 36 (8.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
ANAEMIA			
subjects affected / exposed	24 / 36 (66.67%)	6 / 8 (75.00%)	1 / 2 (50.00%)
occurrences (all)	41	7	1
COAGULOPATHY			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
HYPERLEUKOCYTOSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	10 / 36 (27.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	19	3	0
SPLENOMEGALY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	9 / 36 (25.00%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	21	2	0
LYMPHOPENIA			
subjects affected / exposed	7 / 36 (19.44%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	13	0	0
LYMPHADENOPATHY			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	7 / 36 (19.44%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	13	1	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	7 / 36 (19.44%)	2 / 8 (25.00%)	1 / 2 (50.00%)
occurrences (all)	7	4	1
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 36 (2.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
ANAL INCONTINENCE			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
ANAL FISSURE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ANAL INFLAMMATION			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	18 / 36 (50.00%)	4 / 8 (50.00%)	1 / 2 (50.00%)
occurrences (all)	25	5	3
CONSTIPATION			
subjects affected / exposed	9 / 36 (25.00%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	14	1	1
CHEILITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
FAECALOMA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
DRY MOUTH			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
FLATULENCE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
FOOD POISONING			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX			

DISEASE			
subjects affected / exposed	2 / 36 (5.56%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GINGIVAL HYPERTROPHY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OESOPHAGITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ODYNOPHAGIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
OBSTRUCTION GASTRIC			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	19 / 36 (52.78%)	6 / 8 (75.00%)	2 / 2 (100.00%)
occurrences (all)	33	12	3
ORAL BLOOD BLISTER			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL DISORDER			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	6 / 36 (16.67%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	9	5	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
PROCTALGIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
PROCTITIS			
subjects affected / exposed	1 / 36 (2.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
TOOTH LOSS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	26 / 36 (72.22%)	4 / 8 (50.00%)	1 / 2 (50.00%)
occurrences (all)	62	10	1
Hepatobiliary disorders			
HEPATOMEGALY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HEPATIC FAILURE			

subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
HEPATIC CYTOLYSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	9 / 36 (25.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	9	0	1
DRY SKIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
URTICARIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

PRURITUS			
subjects affected / exposed	5 / 36 (13.89%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	5	1	1
PURPURA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
PROTEINURIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	5 / 36 (13.89%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
RENAL FAILURE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	1 / 36 (2.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
GLYCOSURIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			

ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CUSHINGOID			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	5 / 36 (13.89%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	5	0	2
BACK PAIN			
subjects affected / exposed	3 / 36 (8.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
FLANK PAIN			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
BONE PAIN			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PAIN IN JAW			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	8 / 36 (22.22%)	2 / 8 (25.00%)	1 / 2 (50.00%)
occurrences (all)	10	2	1
NECK PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			

subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
MYALGIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
MYOSITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
SPINAL PAIN			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BLASTOCYSTIS INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
BACTEROIDES INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ADENOVIRUS INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 36 (2.78%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
CORONAVIRUS INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

CONJUNCTIVITIS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
CLOSTRIDIAL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
ENTEROCOLITIS INFECTIOUS			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
GINGIVITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HERPES SIMPLEX			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
NAIL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION FUNGAL			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
LARYNGITIS			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
ORAL CANDIDIASIS			

subjects affected / exposed	2 / 36 (5.56%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
OTITIS MEDIA ACUTE			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RHINOVIRUS INFECTION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
RHINITIS			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA FUNGAL			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
PNEUMONIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
SKIN INFECTION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	3 / 36 (8.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	5	1	0
VIRAL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 36 (8.33%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	3	1	0

STREPTOCOCCAL INFECTION			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	13 / 36 (36.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	20	2	0
DEHYDRATION			
subjects affected / exposed	2 / 36 (5.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERNATRAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	4 / 36 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
HYPERCALCAEMIA			

subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	8 / 36 (22.22%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	10	0	0
HYPERVOLAEMIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HYPERURICAEMIA			
subjects affected / exposed	1 / 36 (2.78%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
HYPOCALCAEMIA			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	11 / 36 (30.56%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	13	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 36 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
HYPONATRAEMIA			
subjects affected / exposed	3 / 36 (8.33%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	6	0	0
REFEEDING SYNDROME			
subjects affected / exposed	0 / 36 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	6 / 36 (16.67%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	10	0	0

Non-serious adverse events	Solid tumors venetoclax 400 mg intermittent	Solid tumors venetoclax 800 mg intermittent	Solid tumors Part 1 Dose Determination
Total subjects affected by non-serious adverse events			

subjects affected / exposed	4 / 4 (100.00%)	5 / 5 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN PAPILLOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPERTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
HAEMATOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VENOUS HAEMORRHAGE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
CATHETER SITE HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE IRRITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
AXILLARY PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
CHILLS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
FACE OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LOCALISED OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
GENERALISED OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	1 / 4 (25.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	1	2	2
MEDICAL DEVICE SITE ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PUNCTURE SITE PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PERINEAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OEDEMA GENITAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			

DYSPNOEA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
COUGH			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	2 / 4 (50.00%)
occurrences (all)	1	1	2
ATELECTASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
RHINORRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
TACHYPNOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
PULMONARY OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
NASAL CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LARYNGEAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1

Psychiatric disorders			
DEPRESSED MOOD			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
AGITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INITIAL INSOMNIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
IRRITABILITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD CORTICOTROPHIN DECREASED			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0

BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CORTISOL DECREASED			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
CARDIAC MURMUR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

BLOOD FIBRINOGEN DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FLUID BALANCE POSITIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMOGLOBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PROTHROMBIN TIME PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	1 / 4 (25.00%)	4 / 5 (80.00%)	2 / 4 (50.00%)
occurrences (all)	1	11	4
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	2 / 4 (50.00%)	3 / 5 (60.00%)	2 / 4 (50.00%)
occurrences (all)	3	7	2
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 4 (25.00%)	3 / 5 (60.00%)	2 / 4 (50.00%)
occurrences (all)	1	4	4
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HAPTOGLOBIN DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
WHITE BLOOD CELL COUNT DECREASED			

subjects affected / exposed	2 / 4 (50.00%)	4 / 5 (80.00%)	2 / 4 (50.00%)
occurrences (all)	3	7	4
WEIGHT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	2
SERUM FERRITIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ALLERGIC TRANSFUSION REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
FALL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PRODUCT USE COMPLAINT			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
STOMA SITE ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VASCULAR ACCESS COMPLICATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WOUND SECRETION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
FANCONI SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
CONGENITAL POIKILODERMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
BRADYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SINUS BRADYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
DYSGEUSIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	2 / 4 (50.00%)
occurrences (all)	0	2	3
HYPOAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
LETHARGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PARAESTHESIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SPINAL CORD COMPRESSION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ANAEMIA			
subjects affected / exposed	4 / 4 (100.00%)	4 / 5 (80.00%)	2 / 4 (50.00%)
occurrences (all)	6	7	3

COAGULOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERLEUKOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
SPLENOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	3 / 4 (75.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	14	0	0
LYMPHOPENIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
PERIORBITAL OEDEMA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	2	0	4
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ANAL INCONTINENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ANAL FISSURE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ANAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	2 / 4 (50.00%)
occurrences (all)	3	1	3
CONSTIPATION			
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	3 / 4 (75.00%)
occurrences (all)	3	1	4
CHEILITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ASCITES			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
APHTHOUS ULCER			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

FAECALOMA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
DYSPEPSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
FOOD POISONING			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
GASTRITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
GINGIVAL HYPERTROPHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
OESOPHAGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ODYNOPHAGIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
OBSTRUCTION GASTRIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
NAUSEA			
subjects affected / exposed	3 / 4 (75.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	5	2	2
ORAL BLOOD BLISTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ORAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TOOTH LOSS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
VOMITING			
subjects affected / exposed	4 / 4 (100.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	6	0	2
Hepatobiliary disorders			
HEPATOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HEPATIC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HEPATIC CYTOLYSIS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
DRY SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
URTICARIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
PURPURA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
PROTEINURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
HYDRONEPHROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
HAEMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2

RENAL FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GLYCOSURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CUSHINGOID			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
BACK PAIN			
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
GROIN PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
FLANK PAIN			

subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
BONE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PAIN IN JAW			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
NECK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MYOSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
BLASTOCYSTIS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
BACTEROIDES INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

ADENOVIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
CORONAVIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
CLOSTRIDIAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ENTEROCOLITIS INFECTIOUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
GASTROENTERITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2

HERPES SIMPLEX			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NAIL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT INFECTION FUNGAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA ACUTE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RHINOVIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA FUNGAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
PHARYNGITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
VIRAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
STREPTOCOCCAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERPHOSPHATAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPERNATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	1	3	1
HYPERVOLAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	2 / 4 (50.00%)
occurrences (all)	1	1	4
HYPOMAGNESAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
HYPONATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	3 / 5 (60.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	3
REFEEDING SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	3

Non-serious adverse events	Other tumors venetoclax 800 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 11 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
SKIN PAPILLOMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
HYPOTENSION			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	3		
HYPERTENSION			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
HAEMATOMA			

subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
VENOUS HAEMORRHAGE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
CATHETER SITE HAEMORRHAGE			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
CATHETER SITE IRRITATION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CHEST PAIN			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
ASTHENIA			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
AXILLARY PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CHILLS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
FACE OEDEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
MALAISE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
LOCALISED OEDEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
INJECTION SITE BRUISING			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
GENERALISED OEDEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
GAIT DISTURBANCE			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
FATIGUE			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	4		
MEDICAL DEVICE SITE ERYTHEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PUNCTURE SITE PAIN			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
PAIN			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
OEDEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PYREXIA			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	5		
Immune system disorders			

DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PERINEAL PAIN			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
OEDEMA GENITAL			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
COUGH			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	3		
ATELECTASIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
RHINORRHOEA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
TACHYPNOEA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PULMONARY OEDEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PLEURAL EFFUSION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
OROPHARYNGEAL PAIN			

subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
NASAL CONGESTION			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
LARYNGEAL INFLAMMATION			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
HYPOXIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
EPISTAXIS			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
Psychiatric disorders			
DEPRESSED MOOD			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CONFUSIONAL STATE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ANXIETY			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
AGITATION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
INITIAL INSOMNIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
IRRITABILITY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
INSOMNIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		

Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
BLOOD CORTICOTROPHIN DECREASED			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	5		
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	5		
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	4		
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
CORTISOL DECREASED			

subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
CARDIAC MURMUR				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
C-REACTIVE PROTEIN INCREASED				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
BLOOD URIC ACID INCREASED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
BLOOD LACTATE DEHYDROGENASE INCREASED				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
BLOOD FIBRINOGEN DECREASED				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
FLUID BALANCE POSITIVE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
GAMMA-GLUTAMYLTRANSFERASE INCREASED				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	3			
HAEMOGLOBIN INCREASED				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
PROTHROMBIN TIME PROLONGED				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
PLATELET COUNT DECREASED				
subjects affected / exposed	7 / 11 (63.64%)			
occurrences (all)	19			
NEUTROPHIL COUNT DECREASED				

subjects affected / exposed	7 / 11 (63.64%)		
occurrences (all)	19		
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	10 / 11 (90.91%)		
occurrences (all)	19		
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HAPTOGLOBIN DECREASED			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	10 / 11 (90.91%)		
occurrences (all)	20		
WEIGHT INCREASED			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
WEIGHT DECREASED			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	3		
SERUM FERRITIN INCREASED			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
ALLERGIC TRANSFUSION REACTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CONTUSION			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
FALL			

subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PROCEDURAL PAIN			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
PRODUCT USE COMPLAINT			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
STOMA SITE ERYTHEMA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
VASCULAR ACCESS COMPLICATION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
WOUND SECRETION			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Congenital, familial and genetic disorders			
FANCONI SYNDROME			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CONGENITAL POIKILODERMA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Cardiac disorders			
BRADYCARDIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PALPITATIONS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PERICARDIAL EFFUSION			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
TACHYCARDIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
SINUS TACHYCARDIA			
subjects affected / exposed	6 / 11 (54.55%)		
occurrences (all)	9		
SINUS BRADYCARDIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
DYSGEUSIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HEADACHE			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	4		
HYPOAESTHESIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
LETHARGY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PARAESTHESIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
TREMOR			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		

SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
SOMNOLENCE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
FEBRILE NEUTROPENIA			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	3		
ANAEMIA			
subjects affected / exposed	9 / 11 (81.82%)		
occurrences (all)	14		
COAGULOPATHY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HYPERLEUKOCYTOSIS			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
NEUTROPENIA			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	8		
SPLENOMEGALY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
THROMBOCYTOPENIA			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
LYMPHOPENIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	3		
LYMPHADENOPATHY			

subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
LEUKOCYTOSIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
LEUKOPENIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	4		
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ANAL INCONTINENCE			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
ANAL FISSURE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ANAL INFLAMMATION			

subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
DIARRHOEA				
subjects affected / exposed	4 / 11 (36.36%)			
occurrences (all)	6			
CONSTIPATION				
subjects affected / exposed	3 / 11 (27.27%)			
occurrences (all)	4			
CHEILITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
ASCITES				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
APHTHOUS ULCER				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
FAECALOMA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
DYSPEPSIA				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
DRY MOUTH				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
FLATULENCE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
FOOD POISONING				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
GASTRITIS				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	2			
GASTROOESOPHAGEAL REFLUX				

DISEASE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
GINGIVAL BLEEDING				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
LOWER GASTROINTESTINAL HAEMORRHAGE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
INTRA-ABDOMINAL HAEMORRHAGE				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
GINGIVAL HYPERTROPHY				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
MOUTH ULCERATION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
OESOPHAGITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
ODYNOPHAGIA				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
OBSTRUCTION GASTRIC				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
NAUSEA				
subjects affected / exposed	9 / 11 (81.82%)			
occurrences (all)	18			
ORAL BLOOD BLISTER				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
ORAL DISORDER				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
STOMATITIS			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
ORAL DYSAESTHESIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ORAL PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PROCTALGIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
PROCTITIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
TOOTH LOSS			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
TOOTHACHE			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
VOMITING			
subjects affected / exposed	9 / 11 (81.82%)		
occurrences (all)	18		
Hepatobiliary disorders			
HEPATOMEGALY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HEPATIC FAILURE			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HEPATIC CYTOLYSIS			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
DRY SKIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ERYTHEMA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
URTICARIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
SKIN ULCER			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
SKIN HYPERPIGMENTATION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
RASH MACULO-PAPULAR			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	5		
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PETECHIAE			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		

PRURITUS			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	4		
PURPURA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
RASH			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
PROTEINURIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
HYDRONEPHROSIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HAEMATURIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
RENAL FAILURE			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
DYSURIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
CYSTITIS NONINFECTIVE			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
GLYCOSURIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
URINARY RETENTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Endocrine disorders			

ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CUSHINGOID			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
BACK PAIN			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	4		
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
GROIN PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
FLANK PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
BONE PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
PAIN IN JAW			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
PAIN IN EXTREMITY			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	4		
NECK PAIN			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
MUSCULOSKELETAL CHEST PAIN			

subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
MYALGIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
MYOSITIS			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
SPINAL PAIN			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Infections and infestations			
BLASTOCYSTIS INFECTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
BACTEROIDES INFECTION			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
ADENOVIRUS INFECTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CANDIDA INFECTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
CORONAVIRUS INFECTION			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		

CONJUNCTIVITIS				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
CLOSTRIDIAL INFECTION				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
CELLULITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
ENTEROCOLITIS INFECTIOUS				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
GINGIVITIS				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
GASTROENTERITIS VIRAL				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
GASTROENTERITIS				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
HERPES SIMPLEX				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
NAIL INFECTION				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
LOWER RESPIRATORY TRACT INFECTION FUNGAL				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
LARYNGITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
ORAL CANDIDIASIS				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
OTITIS MEDIA ACUTE				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
RHINOVIRUS INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
RHINITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
RASH PUSTULAR				
subjects affected / exposed	2 / 11 (18.18%)			
occurrences (all)	2			
PNEUMONIA FUNGAL				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
PNEUMONIA				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
PHARYNGITIS				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
SKIN INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
URINARY TRACT INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
VIRAL INFECTION				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			

STREPTOCOCCAL INFECTION subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
STAPHYLOCOCCAL INFECTION subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Metabolism and nutrition disorders DECREASED APPETITE subjects affected / exposed occurrences (all)	3 / 11 (27.27%) 5		
DEHYDRATION subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
FLUID RETENTION subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
HYPERTRIGLYCERIDAEMIA subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 2		
HYPERPHOSPHATAEMIA subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
HYPERNATRAEMIA subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
HYPERMAGNESAEMIA subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
HYPERKALAEMIA subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2		
HYPERGLYCAEMIA subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
HYPERCALCAEMIA			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HYPOALBUMINAEMIA			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	5		
HYPERVOLAEMIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
HYPERURICAEMIA			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
HYPOCALCAEMIA			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	6		
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HYPOKALAEMIA			
subjects affected / exposed	5 / 11 (45.45%)		
occurrences (all)	10		
HYPOMAGNESAEMIA			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	3		
HYPONATRAEMIA			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	4		
REFEEDING SYNDROME			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
HYPOPHOSPHATAEMIA			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	7		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 October 2017	Amendment 1 -Clarified that subjects in Part 1 with relapsed/refractory malignancies must not have available curative treatment options to be eligible for study -Updated Part 1 Dose Escalation Guidelines to specify that a minimum of 3 subjects will have bone marrow involvement and a minimum of 3 subjects will not have bone marrow involvement -Clarified participation of Germany in Part 2 only -Updated contraception recommendations to include addition of a barrier method for women using hormonal contraceptives -Clarified that tumor assessments will be performed according to the specified criteria for each tumor type -Specified that blood samples are mandatory if part of routine blood draw -Defined a low-fat meal and provided a formula for calculation -Added that cerebrospinal fluid analysis is exploratory -Clarified that plasma concentration or CSF concentration of possible venetoclax metabolites may be determined using validated or non-validated methods -Specified assessments for subjects who are deriving clinical benefit and stay on venetoclax therapy beyond the 9 month duration -Noted that subjects with TCF3-HLF ALL require distinct chemotherapy regimens than those already listed in the protocol -Updated and clarified adverse event reporting and documentation process -Updated Dose-Limiting Toxicity (DLT) criteria -Defined efficacy endpoints that will be assessed -Clarified that diagnosis of TCF3-HLF positive ALL should be confirmed prior to study entry -Specified MRD assessments for subjects with TCF3-HLF positive ALL -Included dosing information for venetoclax target doses for use in combination with certain chemotherapies or if target dose is de-escalated or escalated in Part 1 (Appendix M) and target doses when co-administered with moderate and strong CYP3A inhibitors (Appendix N) -Updated Appendix R with new International Neuroblastoma Response Criteria

23 February 2018	Amendment 2 -Updated the number of subjects enrolled in the study -Updated the timing of study drug administration to allow flexibility for dosing -Clarified that subjects with confirmed TCF3-HLF ALL and BCL-2 expression will enroll in the fifth cohort -Clarified the criteria to begin the second stage of enrollment into individual cohorts -Clarified CNS disease is to be confirmed by lumbar puncture in order to obtain results from CSF sample collection -Updated Section 5.2.1 Part 1 (Dose Determination) to specify the minimum number of subjects in each age group: < 2, 2 –11, and 12 –17 years of age -Clarified in Part 2 (cohort expansion portion) that archived scans within 42 days of enrollment are allowed -Noted that subjects should not receive a live vaccine before (4 weeks before) or during treatment, unless in discussion with the AbbVie TA MD -Clarified the procedure must be followed for uric acid samples containing rasburicase only -Clarified subjects that have completed the DLT period in Part 1 following discussion with AbbVie TA MD may switch to oral tablets, to add rinse step instruction for 800 mg dose preparation, and to clarify that patients must take all of the solution and rinses within 60 minutes of preparation -Clarified venetoclax dose should be withheld if persistent blood chemistry change suggestive of TLS is reported -Included additional DLT criteria stating Grade 4 neutropenia or thrombocytopenia lasting ≥42 days from the start of venetoclax in the absence of evidence of active leukemia -Added diltiazem and removed azithromycin based on recent data that supports inclusion and exclusion respectively
19 October 2018	Amendment 3 -Increased the number of subjects to be enrolled to 165 -Added a 400 mg and 600 mg adult-equivalent target dose of venetoclax tablet for those with solid tumors -Incorporated the addition of the Dose Escalation/De-escalation for solid tumors in Part 1 -Provided guidance on how to manage Grade 3 and 4 neutropenia and thrombocytopenia in solid tumor subjects -Added Section 5.1.2.1 Part 1 –Dose Escalation/De-escalation in Neuroblastoma and Solid Tumor Patients (Cohorts S1, S2, S_ 1, S_ 2) to include a Dose Escalation/De-escalation for solid tumor subjects in Part 1 -Clarified required time points for clinical laboratory tests -Updated venetoclax dosing to allow for combination therapy earlier for relapsed and/or refractory tumors in pediatric patients -Updated rinse volumes for certain doses were updated and/or the second rinse was removed based on newly generated analytic data supporting the change -Revised dosing instructions for venetoclax tablets for oral suspension and added instructions for venetoclax oral tablets -Increased dose of chemotherapy from a palliative dose to a standard dose tolerated by pediatric subjects -Allowed a one-time switch of the chemotherapy regimen for AML and ALL subjects -Updated Appendix H Pharmacokinetic Sampling for Subjects with ALL, AML, or NHL in Part 2 (Cohort Expansion) to add Day 8 Intensive PK sampling -Updated Appendix I Pharmacokinetic Sampling For Subjects with Solid Tumors (Excluding NHL) -Updated Appendix M Age and Weight Adjusted Adult-Equivalent Venetoclax dose and Appendix N Adult Equivalent Venetoclax Doses When Moderate and Strong CYP3A Inhibitors are Administered Concomitantly

25 June 2019	Amendment 4 -Added myeloid growth factor to the treatment options to minimize neutropenia and thrombocytopenia; Table 5 was revised to provide further guidance on the dose and duration of venetoclax and chemotherapy following hematologic toxicity -Updated Inclusion Criteria to add hepatic function criteria for subjects who previously received inotuzumab ozogamicin within 30 days of the first dose of study drug -Modified Exclusion Criteria number 2 to only exclude subjects with CNS disease with cranial involvement requiring radiation; Criteria number 3 was changed to exclude subjects who were treated with inotuzumab ozogamicin within 30 days of the first dose of study drug and to add exception for Ph+ ALL patients receiving TKI anti-cancer therapies -Updated Section 5.2.4 Contraceptive Recommendations to add surgical sterilization for females and vasectomy for males as acceptable contraceptive methods -Updated Sections 6.1.3 Relationship to Study Drug and Section 6.1.4 Adverse Event Collection Period -Updated Section 6.1.8 Toxicity Management for Dose Limiting Toxicities to update the DLT criteria for patients with NHL, neuroblastoma, and other solid tumors -Updated Appendix H Pharmacokinetic Sampling for Subjects with ALL, AML, or NHL to clarify the pharmacokinetic sampling requirements for neonates -Updated Appendix N Table. Adult-Equivalent Venetoclax Doses (mg) When Moderate and Strong CYP3A Inhibitors are Administered Concomitantly, to correct the dose for subjects with hematologic malignancies using the 800 mg adult equivalent dose weighing ≥45 kg on day 1 of the dose ramp up, from 25 mg to 30 mg -Updated Section 5.5.2 Chemotherapy Administered to include subjects who experience an acute lineage switch while on study or present with mixed lineage leukemia prior to enrollment the option to be treated using chemotherapy options for either AML or ALL
09 March 2021	Amendment 5 -Revised TLS prophylaxis requirements for subjects with solid tumors -Increased number of subjects projected to enroll from 30 to 45 -Clarified that in Part 2, neuroblastoma and solid tumor subjects are not required to recover neutrophil and platelet counts to start the next cycle of combination therapy -Clarified that agents that increase platelet production may be administered -Provided flexibility for subjects on the intermittent dosing schedule -Added gemtuzumab ozogamicin to inclusion criteria number 3 -Clarified that subjects with TCF3-HLF-ALL in the fifth cohort are not required to have evidence of BCL-2 expression -Allowed for collection of labs prior to consent; clarified review of the Day 1 pre-dose labs when Day −1 labs are found to be clinically acceptable; replaced wording of "liquid tumor" with hematologic malignancies/NHL; revised TLS lab collection timepoints for subjects with solid tumors; clarified labs collected at unscheduled timepoints should be entered into EDC as unscheduled visits -Clarified that in Part 2, neuroblastoma and solid tumor subjects are not required to recover neutrophil and platelet counts to start the next cycle of combination therapy -Updated Appendix D to include other hematologic malignancy patients -Provided guidance on the intermittent dosing schedule regarding labs, scans, venetoclax administration and bone marrow aspirate and/or biopsy; clarified a bone marrow biopsy and/or aspirate is required for subjects with relevant tumor types -Added other hematologic malignancy subjects and clarified W2 Day 8 collection for neonates -Updated Pharmacokinetic Sampling to add cohorts S1 and S2 and remove Part 2 cohort expansion -Incorporated necessary protocol modifications due to the COVID-19 pandemic -Added information that remote monitoring may be employed as needed

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported