Clinical trial results:
A Phase Ib/II Multi-Arm Study with Venetoclax in Combination with Cobimetinib and Venetoclax in Combination with Idasanutlin in Patients with Relapsed or Refractory Acute Myeloid Leukemia Who Are Not Eligible for Cytotoxic Therapy

Summary

EudraCT number	2015-003386-28
Trial protocol	FR IT
Global end of trial date	10 December 2020

Results information

Result version number	v1 (current)
This version publication date	21 December 2021
First version publication date	21 December 2021

Trial information

Trial identification

Sponsor protocol code	GH29914

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02670044
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 December 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 December 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of Venetoclax in combination with Cobimetinib and Venetoclax in combination with Idasanutlin

Protection of trial subjects:

All subjects were required to sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 March 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 18
Country: Number of subjects enrolled	France: 14
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	United States: 44
Worldwide total number of subjects	88
EEA total number of subjects	26

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	11

From 65 to 84 years	72
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 17 centers in 4 countries.

Pre-assignment

Screening details:

A total of 88 subjects were randomized in this study. Of these, 85 subjects received at least one dose of any study drug.

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	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)

Arm description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Cobimetinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Cobimetinib was administered orally once daily (QD) at a dose of 40mg on Days 1-21 of each 28-day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 400mg on Days 1-28 of each 28 day treatment cycle.

Arm title	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)

Arm description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 600mg on Days 1-28 of each 28 day treatment cycle.

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

Dosage and administration details:

Cobimetinib was administered orally once daily (QD) at a dose of 40mg on Days 1-21 of each 28-day treatment cycle.

Arm title	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)

Arm description:

Subjects received Venetoclax 800mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Cobimetinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Cobimetinib was administered orally once daily (QD) at a dose of 40mg on Days 1-21 of each 28-day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 800mg on Days 1-28 of each 28 day treatment cycle.

Arm title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)

Arm description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 60mg daily on Days 1-21 of each 28-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Cobimetinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Cobimetinib was administered orally once daily (QD) at a dose of 60mg on Days 1-21 of each 28-day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 400mg on Days 1-28 of each 28 day treatment cycle.

Arm title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)

Arm description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin

200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 400mg on Days 1-28 of each 28 day treatment cycle.

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

Dosage and administration details:

Idasanutlin was administered orally once daily (QD) or twice daily (BID) at a dose of 200mg on Days 1-5 of each 28 day treatment cycle.

Arm title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)

Arm description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 150mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 600mg on Days 1-28 of each 28 day treatment cycle.

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

Dosage and administration details:

Idasanutlin was administered orally once daily (QD) or twice daily (BID) at a dose of 150mg on Days 1-5 of each 28 day treatment cycle.

Arm title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)

Arm description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 600mg on Days 1-28 of each 28 day treatment cycle.

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

Dosage and administration details:

Idasanutlin was administered orally once daily (QD) or twice daily (BID) at a dose of 200mg on Days 1-5 of each 28 day treatment cycle.

Arm title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)

Arm description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 400mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 400mg on Days 1-28 of each 28 day treatment cycle.

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

Dosage and administration details:

Idasanutlin was administered orally once daily (QD) or twice daily (BID) at a dose of 400mg on Days 1-5 of each 28 day treatment cycle.

Arm title	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)

Arm description:

Subjects received Venetoclax 600mg daily on Days 1-21 of each 28 day treatment cycle and Idasanutlin 150mg daily on Days 1-5 of each 28 day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin was administered orally once daily (QD) at a dose of 150mg on Days 1-5 of each 28 day treatment cycle.

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

Dosage and administration details:

Venetoclax was administered orally once daily (QD) at a dose of 600mg on Days 1-21 of each 28 day treatment cycle.

Number of subjects in period 1	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)
Started	4	8	12
Completed	0	1	0
Not completed	4	7	12
Consent withdrawn by subject	-	1	2
Death	4	6	10
Progressive Disease	-	-	-
Multiple Reasons	-	-	-
Study Terminated by Sponsor	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)
Started	8	6	13
Completed	0	1	0
Not completed	8	5	13
Consent withdrawn by subject	-	-	1
Death	6	5	11
Progressive Disease	-	-	1
Multiple Reasons	1	-	-
Study Terminated by Sponsor	-	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)
Started	22	9	6
Completed	3	0	0
Not completed	19	9	6
Consent withdrawn by subject	1	1	-
Death	17	7	2
Progressive Disease	-	-	-
Multiple Reasons	1	-	-
Study Terminated by Sponsor	-	-	4
Lost to follow-up	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)
Reporting group description:	
Subjects received Venetoclax 800mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 60mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 150mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 400mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-21 of each 28 day treatment cycle and Idasanutlin 150mg daily on Days 1-5 of each 28 day treatment cycle.	

Reporting group values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)
Number of subjects	4	8	12
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0

Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	2	1
From 65-84 years	4	6	11
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	72.3	70.9	73.5
standard deviation	± 3.8	± 6.6	± 6.6
Gender Categorical			
Units: Subjects			
Female	2	4	7
Male	2	4	5
Race/Ethnicity, Customized			
Race			
Units: Subjects			
Asian	0	1	1
Black or African American	0	0	2
White	1	7	9
Unknown	3	0	0
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	2	7	11
Not Stated	1	1	0

Reporting group values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)
Number of subjects	8	6	13
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	1	3
From 65-84 years	7	3	10
85 years and over	0	2	0
Age Continuous			
Units: years			
arithmetic mean	70.4	75.8	71.4
standard deviation	± 6.3	± 11.4	± 5.6
Gender Categorical			
Units: Subjects			
Female	2	1	4
Male	6	5	9

Race/Ethnicity, Customized			
Race			
Units: Subjects			
Asian	1	0	0
Black or African American	0	0	1
White	5	6	11
Unknown	2	0	1
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	7	6	9
Not Stated	1	0	2

Reporting group values	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)
Number of subjects	22	9	6
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	1	2
From 65-84 years	19	8	4
85 years and over	3	0	0
Age Continuous			
Units: years			
arithmetic mean	75.1	73.9	63.5
standard deviation	± 7.0	± 6.6	± 14.7
Gender Categorical			
Units: Subjects			
Female	9	4	4
Male	13	5	2
Race/Ethnicity, Customized			
Race			
Units: Subjects			
Asian	1	0	0
Black or African American	0	0	0
White	15	8	6
Unknown	6	1	0
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	15	7	5
Not Stated	7	2	0

Reporting group values	Total		
Number of subjects	88		
Age Categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	11		
From 65-84 years	72		
85 years and over	5		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Subjects			
Female	37		
Male	51		
Race/Ethnicity, Customized			
Race			
Units: Subjects			
Asian	4		
Black or African American	3		
White	68		
Unknown	13		
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
Hispanic or Latino	5		
Not Hispanic or Latino	69		
Not Stated	14		

End points

End points reporting groups

Reporting group title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)
Reporting group description:	
Subjects received Venetoclax 800mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 60mg daily on Days 1-21 of each 28-day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 150mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Reporting group description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 400mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Reporting group title	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)
Reporting group description:	
Subjects received Venetoclax 600mg daily on Days 1-21 of each 28 day treatment cycle and Idasanutlin 150mg daily on Days 1-5 of each 28 day treatment cycle.	
Subject analysis set title	Arm A (Venetoclax + Cobimetinib) (PRO Analysis)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received Venetoclax daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib daily on Days 1-21 of each 28-day treatment cycle.	
Subject analysis set title	Arm B (Venetoclax + Idasanutlin) (PRO Analysis)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received Venetoclax on Days 1-28 of each 28 day treatment cycle and Idasanutlin daily or twice daily on Days 1-5 of each 28 day treatment cycle.	
Subject analysis set title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg) (PK)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.	

Subject analysis set title	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

Subject analysis set title	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 800mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

Subject analysis set title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 60mg daily on Days 1-21 of each 28-day treatment cycle.

Subject analysis set title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Subject analysis set title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 150mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Subject analysis set title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Subject analysis set title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 400mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Subject analysis set title	Dose Optim: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg) (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received Venetoclax 600mg daily on Days 1-21 of each 28 day treatment cycle and Idasanutlin 150mg daily on Days 1-5 of each 28 day treatment cycle.

Primary: Number of Subjects with Dose Limiting Toxicities (DLTs)

End point title	Number of Subjects with Dose Limiting Toxicities (DLTs)[1]

End point description:

End point type	Primary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 1 for a minimum of 28 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical analyses performed on safety data.

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	12	7
Units: Subjects				
number (not applicable)	0	1	1	2

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	21	9
Units: Subjects				
number (not applicable)	0	2	2	2

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: Subjects				
number (not applicable)				

Notes:

[2] - Cohort was not assessed for DLTs. Not considered part of dose escalation.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Adverse Events (AEs), Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESIs)

End point title	Number of Subjects with Adverse Events (AEs), Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESIs)[3]

End point description:

End point type	Primary

End point timeframe:

Baseline up until 30 days after the last dose of study drug (up to a maximum of 4 years, 9 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical analyses performed on safety data.

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	12	7
Units: Subjects				
number (not applicable)				
AEs	4	7	12	7
SAEs	2	4	11	7
AESIs	3	5	11	6

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	21	9
Units: Subjects				
number (not applicable)				
AEs	6	13	21	9
SAEs	5	11	16	8
AESIs	4	11	15	7

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Subjects				
number (not applicable)				
AEs	6			
SAEs	5			
AESIs	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) (Complete remission (CR) + Complete Remission with Incomplete Blood Count Recovery (CRi) + Incomplete Platelet Count Recovery (CRp) + Partial Remission/Partial Response [PR])

End point title	Overall Response Rate (ORR) (Complete remission (CR) + Complete Remission with Incomplete Blood Count Recovery (CRi) + Incomplete Platelet Count Recovery (CRp) + Partial Remission/Partial Response [PR])

End point description:

ORR is defined as the proportion of subjects who achieved a CR, CRi, CRp or partial remission/partial response (PR).

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	8	12	8
Units: Subjects				
number (not applicable)	1	1	2	1

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	22	9
Units: Subjects				
number (not applicable)	1	5	7	1

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Subjects				
number (not applicable)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Complete remission/complete response (CR) + Complete remission with incomplete blood count recovery (CRi) + Complete remission with incomplete platelet count recovery (CRp)

End point title	Complete remission/complete response (CR) + Complete remission with incomplete blood count recovery (CRi) + Complete remission with incomplete platelet count recovery (CRp)

End point description:

Defined as the proportion of subjects who achieved a CR, CRi, or CRp.

End point type	Secondary

End point timeframe:

Up to 2 years.

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	8	12	8
Units: Subjects				
number (not applicable)	1	1	2	1

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	22	9
Units: Subjects				
number (not applicable)	1	5	7	0

End point values	Dose Optimisation: Arm B (Ven			

	600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Subjects				
number (not applicable)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: CR + Complete Remission with Partial Hematologic Recovery (CRh) Rate

End point title	CR + Complete Remission with Partial Hematologic Recovery (CRh) Rate

End point description:

Please note that for this Outcome Measure, an insufficient number of subjects were analysed meaning that the data collected was minimal and not sufficient to generate the Statistical (Number) values.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[4]	0[5]	0[6]	0[7]
Units: Subjects				
number (not applicable)				

Notes:

[4] - Insufficient number of subjects analysed.

[5] - Insufficient number of subjects analysed.

[6] - Insufficient number of subjects analysed.

[7] - Insufficient number of subjects analysed.

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[8]	0[9]	0[10]	0[11]
Units: Subjects				
number (not applicable)				

Notes:

[8] - Insufficient number of subjects analysed.

[9] - Insufficient number of subjects analysed.

[10] - Insufficient number of subjects analysed.

[11] - Insufficient number of subjects analysed.

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[12]			
Units: Subjects				
number (not applicable)				

Notes:

[12] - Insufficient number of subjects analysed.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

DOR is defined as the number of days from the date of first response (CR, CRi, CRp or PR) to the earliest recurrence, disease progression or death.

0000/9999 = Not Estimable.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	1
Units: Months				
median (confidence interval 95%)	2.0 (0000 to 9999)	4.4 (0000 to 9999)	2.6 (1.0 to 4.2)	10.4 (0000 to 9999)

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida	Dose Escalation: Arm B (Venetoclax 600mg + Ida	Dose Escalation: Arm B (Venetoclax 600mg + Ida	Dose Escalation: Arm B (Venetoclax 400mg + Ida

	200mg)	150mg)	200mg)	400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	5	7	1
Units: Months				
median (confidence interval 95%)	9999 (0000 to 9999)	6.0 (2.2 to 12.5)	4.9 (1.9 to 8.8)	0.6 (0000 to 9999)

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Months				
median (confidence interval 95%)	9999 (1.0 to 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Progression (TTP)

End point title	Time to Progression (TTP)

End point description:

TTP is defined as the number of days from the date of first treatment to the date of earliest disease progression.

0000/9999 = Not Estimable.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	4	0[13]
Units: Months				
median (confidence interval 95%)	4.9 (0000 to 9999)	4.5 (3.2 to 5.8)	2.8 (0.9 to 7.4)	(to)

Notes:
[13] - No subjects analysed in this arm.

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	13	2
Units: Months				
median (confidence interval 95%)	1.7 (0.9 to 6.7)	7.1 (3.0 to 12.4)	4.4 (3.3 to 5.9)	7.7 (1.2 to 14.2)

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Months				
median (confidence interval 95%)	3.8 (1.8 to 5.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)

End point description:

Please note that for this Outcome Measure, an insufficient number of PFS Events meant that this insufficient data could not be analysed and therefore, the Statistical (Median and Lower Limit/Upper Limit Confidence Interval (CI)) values could not be generated.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[14]	0[15]	0[16]	0[17]

Units: Months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[14] - No subjects were analysed for median and CI.

[15] - No subjects were analysed for median and CI.

[16] - No subjects were analysed for median and CI.

[17] - No subjects were analysed for median and CI.

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[18]	0[19]	0[20]	0[21]
Units: Months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[18] - No subjects were analysed for median and CI.

[19] - No subjects were analysed for median and CI.

[20] - No subjects were analysed for median and CI.

[21] - No subjects were analysed for median and CI.

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[22]			
Units: Months				
median (confidence interval 95%)	(to)			

Notes:

[22] - No subjects were analysed for median and CI.

Statistical analyses

No statistical analyses for this end point

Secondary: Event-Free Survival (EFS)

End point title	Event-Free Survival (EFS)

End point description:

EFS is defined for all subjects and measured from the date of first treatment until treatment failure, relapse from CR, CRp or CRi or death from any cause, whichever occurs first.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	8	12	8
Units: Months				
median (confidence interval 95%)	0.9 (0.9 to 4.7)	2.8 (1.6 to 3.2)	2.5 (1.4 to 7.1)	1.8 (1.0 to 12.3)

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	22	9
Units: Months				
median (confidence interval 95%)	1.9 (1.7 to 6.7)	3.8 (3.2 to 6.2)	3.6 (2.3 to 5.5)	2.8 (1.5 to 4.4)

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Months				
median (confidence interval 95%)	3.8 (1.8 to 5.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Leukemia-Free Survival (LFS)

End point title	Leukemia-Free Survival (LFS)

End point description:

Please note that for this Outcome Measure, an insufficient number of LFS Events meant that this insufficient data could not be analysed and therefore, the Statistical (Median and Lower Limit/Upper Limit Confidence Interval (CI)) values could not be generated.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[23]	0[24]	0[25]	0[26]
Units: Months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[23] - No subjects were analysed for median and CI.

[24] - No subjects were analysed for median and CI.

[25] - No subjects were analysed for median and CI.

[26] - No subjects were analysed for median and CI.

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[27]	0[28]	0[29]	0[30]
Units: Months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[27] - No subjects were analysed for median and CI.

[28] - No subjects were analysed for median and CI.

[29] - No subjects were analysed for median and CI.

[30] - No subjects were analysed for median and CI.

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[31]			
Units: Months				
median (confidence interval 95%)	(to)			

Notes:

[31] - No subjects were analysed for median and CI.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS was defined as the number of days from the date of first treatment to the date of death from any cause for all subjects.

9999 = Not Estimable.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	8	12	8
Units: Months				
median (confidence interval 95%)	4.7 (1.6 to 8.7)	5.9 (2.1 to 14.2)	3.4 (1.6 to 9.3)	2.8 (1.0 to 8.6)

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	22	9
Units: Months				
median (confidence interval 95%)	2.3 (1.9 to 10.2)	5.3 (3.4 to 13.7)	6.3 (3.9 to 9.8)	3.1 (1.8 to 4.4)

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Months				
median (confidence interval 95%)	9999 (4.1 to 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of Venetoclax Area Under the Concentration-Time Curve from Time Zero to Last Measurable Concentration (AUC0-24hr)

End point title	Pharmacokinetics of Venetoclax Area Under the Concentration-Time Curve from Time Zero to Last Measurable Concentration (AUC0-24hr)

End point description:

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	7	8	3
Units: µg·hr/mL				
arithmetic mean (full range (min-max))	20.8 (11.2 to 30.0)	21.7 (7.54 to 43.0)	24.9 (13.4 to 47.3)	22.9 (18.2 to 29.2)

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	11	19	8
Units: µg·hr/mL				
arithmetic mean (full range (min-max))	14.9 (3.68 to 31.5)	21.6 (7.76 to 50.1)	16.6 (6.03 to 34.5)	22.2 (3.46 to 80.7)

End point values	Dose Optim: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg) (PK)			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: µg·hr/mL				
arithmetic mean (full range (min-max))	21.8 (10.1 to 33.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of Venetoclax Maximum Observed Concentration (Cmax)

End point title	Pharmacokinetics of Venetoclax Maximum Observed Concentration (Cmax)

End point description:

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	7	8	3
Units: µg/mL				
arithmetic mean (full range (min-max))	1.34 (0.85 to 1.65)	1.48 (0.88 to 2.43)	1.64 (0.80 to 2.90)	1.16 (0.96 to 1.43)

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	11	19	8
Units: µg/mL				
arithmetic mean (full range (min-max))	1.11 (0.26 to 1.88)	1.47 (0.69 to 3.54)	1.15 (0.34 to 2.09)	1.04 (0.22 to 1.95)

End point values	Dose Optim: Arm B (Ven 600mg (Day 1 to 21) + Ida			

	150mg) (PK)			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: µg/mL				
arithmetic mean (full range (min-max))	1.45 (0.74 to 2.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of Cobimetinib Area Under the Concentration-Time Curve from Time Zero to Last Measurable Concentration (AUC0-24hr)

End point title	Pharmacokinetics of Cobimetinib Area Under the Concentration-Time Curve from Time Zero to Last Measurable Concentration (AUC0-24hr)

End point description:

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	7	8	3
Units: µg·hr/mL				
arithmetic mean (full range (min-max))	5.30 (2.40 to 12.9)	3.21 (0.46 to 5.51)	6.34 (2.25 to 11.7)	12.6 (6.0 to 16.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of Cobimetinib Maximum Observed Concentration (Cmax)

End point title	Pharmacokinetics of Cobimetinib Maximum Observed Concentration (Cmax)

End point description:

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg) (PK)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	7	8	3
Units: µg/mL				
arithmetic mean (full range (min-max))	0.32 (0.16 to 0.76)	0.20 (0.089 to 0.30)	0.39 (0.20 to 0.62)	0.64 (0.31 to 0.81)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of Idasanutlin Area Under the Concentration-Time Curve from Time Zero to Last Measurable Concentration (AUC0-24hr)

End point title	Pharmacokinetics of Idasanutlin Area Under the Concentration-Time Curve from Time Zero to Last Measurable Concentration (AUC0-24hr)
End point description:	
End point type	Secondary
End point timeframe: Up to 6 months	

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	11	19	8
Units: µg·hr/mL				
arithmetic mean (full range (min-max))	66.2 (19.2 to 142)	67.5 (24.3 to 135)	70.1 (29.6 to 124)	132 (32.5 to 280)

End point values	Dose Optim: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg) (PK)			

Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: µg·hr/mL				
arithmetic mean (full range (min-max))	59.1 (30.6 to 73.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of Idasanutlin Maximum Observed Concentration (Cmax)

End point title	Pharmacokinetics of Idasanutlin Maximum Observed Concentration (Cmax)

End point description:

End point type	Secondary

End point timeframe:

Up to 6 months

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg) (PK)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg) (PK)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg) (PK)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	11	19	8
Units: µg/mL				
arithmetic mean (full range (min-max))	3.77 (1.16 to 8.74)	3.76 (1.63 to 7.42)	4.13 (1.51 to 7.37)	7.11 (1.39 to 16.3)

End point values	Dose Optim: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg) (PK)			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: µg/mL				
arithmetic mean (full range (min-max))	3.22 (1.86 to 3.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Symptoms in Patient-Reported Outcomes of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) Questionnaire

End point title	Number of Subjects Reporting Symptoms in Patient-Reported Outcomes of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) Questionnaire

End point description:

(n=X; n=X) represents the number of subjects analysed at each timepoint.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Arm A (Venetoclax + Cobimetinib) (PRO Analysis)	Arm B (Venetoclax + Idasanutlin) (PRO Analysis)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15	11		
Units: Subjects				
number (not applicable)				
Nausea frequency (n=14; n=9)	63.6	52.9		
Diarrhoea frequency (n=15; n=11)	68.2	64.7		
Decreased appetite severity (n=14; n=10)	63.6	58.8		
Vomiting severity (n=8; n=8)	36.4	47.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of Transfusion Independence

End point title	Rate of Transfusion Independence

End point description:

Please note that for this Outcome Measure, an insufficient number of subjects were analysed meaning that the data collected was minimal and not sufficient to generate the Statistical (Number) values.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[32]	0[33]	0[34]	0[35]
Units: Subjects				
number (not applicable)				

Notes:

[32] - Insufficient number of subjects analysed.

[33] - Insufficient number of subjects analysed.

[34] - Insufficient number of subjects analysed.

[35] - Insufficient number of subjects analysed.

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[36]	0[37]	0[38]	0[39]
Units: Subjects				
number (not applicable)				

Notes:

[36] - Insufficient number of subjects analysed.

[37] - Insufficient number of subjects analysed.

[38] - Insufficient number of subjects analysed.

[39] - Insufficient number of subjects analysed.

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[40]			
Units: Subjects				
number (not applicable)				

Notes:

[40] - Insufficient number of subjects analysed.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration Of Transfusion Independence, Defined As The Number Of Consecutive Days Of Transfusion Independence, Measured From 1 Day After Last Transfusion To Disease Progression Or Subsequent Transfusion

End point title	Duration Of Transfusion Independence, Defined As The Number Of Consecutive Days Of Transfusion Independence, Measured From 1 Day After Last Transfusion To Disease Progression Or Subsequent Transfusion

End point description:

Please note that for this Outcome Measure, an insufficient number of subjects were analysed meaning that the data collected was minimal and not sufficient to generate the Statistical (Number) values.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[41]	0[42]	0[43]	0[44]
Units: Days				
number (not applicable)				

Notes:

[41] - Insufficient number of subjects analysed.

[42] - Insufficient number of subjects analysed.

[43] - Insufficient number of subjects analysed.

[44] - Insufficient number of subjects analysed.

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[45]	0[46]	0[47]	0[48]
Units: Days				
number (not applicable)				

Notes:

[45] - Insufficient number of subjects analysed.

[46] - Insufficient number of subjects analysed.

[47] - Insufficient number of subjects analysed.

[48] - Insufficient number of subjects analysed.

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[49]			
Units: Days				
number (not applicable)				

Notes:

[49] - Insufficient number of subjects analysed.

Statistical analyses

No statistical analyses for this end point

Secondary: Minimal Residual Disease (MRD) In The Bone Marrow To Evaluate The Depth Of Response

End point title	Minimal Residual Disease (MRD) In The Bone Marrow To Evaluate The Depth Of Response

End point description:

Please note that for this Outcome Measure, an insufficient number of subjects were analysed meaning that the data collected was minimal and not sufficient to generate the Statistical (Number) values.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[50]	0[51]	0[52]	0[53]
Units: Subjects				
number (not applicable)				

Notes:

[50] - Insufficient number of subjects analysed.

[51] - Insufficient number of subjects analysed.

[52] - Insufficient number of subjects analysed.

[53] - Insufficient number of subjects analysed.

End point values	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[54]	0[55]	0[56]	0[57]
Units: Subjects				
number (not applicable)				

Notes:

[54] - Insufficient number of subjects analysed.

[55] - Insufficient number of subjects analysed.

[56] - Insufficient number of subjects analysed.

[57] - Insufficient number of subjects analysed.

End point values	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[58]			
Units: Subjects				

number (not applicable)				

Notes:

[58] - Insufficient number of subjects analysed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up until 30 days after the last dose of study drug (up to a maximum of 4 years, 9 months)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18

Reporting groups

Reporting group title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)

Reporting group description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

Reporting group title	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)

Reporting group description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

Reporting group title	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)

Reporting group description:

Subjects received Venetoclax 800mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 40mg daily on Days 1-21 of each 28-day treatment cycle.

Reporting group title	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)

Reporting group description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Cobimetinib 60mg daily on Days 1-21 of each 28-day treatment cycle.

Reporting group title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)

Reporting group description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Reporting group title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)

Reporting group description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 150mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Reporting group title	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)

Reporting group description:

Subjects received Venetoclax 600mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 200mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Reporting group title	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)

Reporting group description:

Subjects received Venetoclax 400mg daily on Days 1-28 of each 28 day treatment cycle and Idasanutlin 400mg daily or twice daily on Days 1-5 of each 28 day treatment cycle.

Reporting group title	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)

Reporting group description:

Subjects received Venetoclax 600mg daily on Days 1-21 of each 28 day treatment cycle and Idasanutlin 150mg daily on Days 1-5 of each 28 day treatment cycle.

Serious adverse events	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	4 / 7 (57.14%)	11 / 12 (91.67%)
number of deaths (all causes)	4	6	10
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			

HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
PROSTATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
PLEURAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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%)	1 / 7 (14.29%)	0 / 12 (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
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
POST PROCEDURAL HAEMATOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 CHRONIC			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (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
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (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
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE CORONARY SYNDROME			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (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 NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	5 / 12 (41.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 MARROW FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
CHALAZION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
CHOLECYSTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
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			
CHONDROCALCINOSIS PYROPHOSPHATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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			
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAL SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HORDEOLUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 NECROTISING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE HAEMORRHAGIC CONJUNCTIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 12 (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
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
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 BACTERIAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC CANDIDA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	5 / 12 (41.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
PNEUMONIA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	3 / 12 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FUNGAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)
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 SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOSPLENIC CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPOPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 12 (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
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	5 / 6 (83.33%)	11 / 13 (84.62%)
number of deaths (all causes)	6	5	13

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (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 PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Reproductive system and breast			

disorders			
PROSTATITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
PLEURAL EFFUSION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (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
Investigations			
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (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
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
POST PROCEDURAL HAEMATOMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC FAILURE CHRONIC			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
CEREBRAL HAEMORRHAGE			

subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	8 / 13 (61.54%)
occurrences causally related to treatment / all	0 / 6	1 / 2	4 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE MARROW FAILURE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
CHALAZION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
DYSPHAGIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (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
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
CHOLECYSTITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
CHONDROCALCINOSIS PYROPHOSPHATE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRALGIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAL SEPSIS			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (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
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOPULMONARY ASPERGILLOSIS			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 13 (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
HORDEOLUM			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA NECROTISING			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE HAEMORRHAGIC CONJUNCTIVITIS			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (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
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 BACTERIAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 BACTERAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC CANDIDA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA FUNGAL			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 5	0 / 2	2 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SEPTIC SHOCK			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA SEPSIS			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOSPLENIC CANDIDIASIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
HYPOPHAGIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (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
DECREASED APPETITE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 21 (76.19%)	8 / 9 (88.89%)	5 / 6 (83.33%)
number of deaths (all causes)	17	7	2
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
ORTHOSTATIC HYPOTENSION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (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
FATIGUE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
PROSTATITIS			

subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
PLEURAL EFFUSION			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (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
DYSPNOEA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
POST PROCEDURAL HAEMATOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
CARDIAC FAILURE CHRONIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVOUS SYSTEM DISORDER			

subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	5 / 21 (23.81%)	3 / 9 (33.33%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	3 / 7	3 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE MARROW FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
CHALAZION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
DYSPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DIARRHOEA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLECYSTITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (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

Musculoskeletal and connective tissue disorders			
CHONDROCALCINOSIS PYROPHOSPHATE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ENTEROCOCCAL INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSEUDOMONAL SEPSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOPULMONARY ASPERGILLOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HORDEOLUM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA NECROTISING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE HAEMORRHAGIC CONJUNCTIVITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA SEPSIS			

subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (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
PNEUMONIA BACTERIAL			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC CANDIDA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOTH INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA FUNGAL			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (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
SEPSIS			
subjects affected / exposed	3 / 21 (14.29%)	3 / 9 (33.33%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 3	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
PNEUMONIA			

subjects affected / exposed	2 / 21 (9.52%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 5	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 21 (0.00%)	2 / 9 (22.22%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FUNGAL INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	1 / 21 (4.76%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA SEPSIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOSPLENIC CANDIDIASIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPOPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DECREASED APPETITE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 600mg + Cobi 40mg)	Dose Escalation: Arm A (Venetoclax 800mg + Cobi 40mg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	7 / 7 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEOPLASM			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
LEUKAEMIA CUTIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

MONOCLONAL GAMMOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
THROMBOPHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PHLEBITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
HYPERTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
PYREXIA			

subjects affected / exposed	0 / 4 (0.00%)	3 / 7 (42.86%)	2 / 12 (16.67%)
occurrences (all)	0	3	2
FATIGUE			
subjects affected / exposed	1 / 4 (25.00%)	6 / 7 (85.71%)	4 / 12 (33.33%)
occurrences (all)	1	6	4
CYST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
LOCALISED OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FACIAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
SUPRAPUBIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
MEDICAL DEVICE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 4 (75.00%)	2 / 7 (28.57%)	0 / 12 (0.00%)
occurrences (all)	3	2	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	3
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
GENITAL LESION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
PROSTATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SCROTAL OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
THROAT IRRITATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RALES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
RHINORRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
TACHYPNOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RHONCHI			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	2 / 12 (16.67%)
occurrences (all)	2	2	2
THROAT TIGHTNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
COUGH			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
WHEEZING			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PULMONARY VASCULAR DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
HAEMOPTYSIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
HICCUPS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DYSPHONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
PLEURITIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PULMONARY MASS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

RESPIRATORY FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
DELIRIUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PROTHROMBIN TIME PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
ANTITHROMBIN III DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
BLOOD CREATINE PHOSPHOKINASE INCREASED			

subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
BREATH SOUNDS ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CARDIAC MURMUR			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SERUM FERRITIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	1 / 12 (8.33%)
occurrences (all)	1	2	1
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
BLOOD LACTIC ACID INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
WEIGHT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
BLOOD CHLORIDE INCREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
TRANSFUSION REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
PERIORBITAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	0	2	2
POST PROCEDURAL FEVER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CONTUSION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cardiac disorders			
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
SINUS BRADYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CARDIAC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nervous system disorders			
TRANSIENT APHASIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
LETHARGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
SYNCOPE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
SOMNOLENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
HEMIPARESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
TREMOR			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
HEADACHE			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
DIABETIC NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPOGEUSIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

COAGULOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
BONE MARROW FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
ANAEMIA			
subjects affected / exposed	2 / 4 (50.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	3	2	1
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	3
THROMBOCYTOPENIA			
subjects affected / exposed	2 / 4 (50.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	2	1	2
LEUKOPENIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
LYMPH NODE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SPLENOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
EAR CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
VITREOUS HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
MACULAR OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
DIABETIC RETINOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
RETINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	2 / 12 (16.67%)
occurrences (all)	0	2	2
VITREOUS DETACHMENT			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
RETINAL DRUSEN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
OPTIC DISC DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
NORMAL TENSION GLAUCOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
BLEPHARITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
CATARACT			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
MELAENA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	7 / 12 (58.33%)
occurrences (all)	1	1	7
VOMITING			
subjects affected / exposed	2 / 4 (50.00%)	2 / 7 (28.57%)	3 / 12 (25.00%)
occurrences (all)	2	2	4
HAEMATOCHEZIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0

TONGUE DISCOLOURATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
ILEUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
DIARRHOEA			
subjects affected / exposed	4 / 4 (100.00%)	5 / 7 (71.43%)	7 / 12 (58.33%)
occurrences (all)	5	14	15
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
ANAL INCONTINENCE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0

GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
GINGIVAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
FLATULENCE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
GINGIVAL HYPERTROPHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
DIVERTICULUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
STOMATITIS			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	2 / 12 (16.67%)
occurrences (all)	1	1	3
DIVERTICULUM GASTRIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
ABDOMINAL PAIN UPPER			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
TOOTHACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
LIP BLISTER			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
NAUSEA			
subjects affected / exposed	2 / 4 (50.00%)	4 / 7 (57.14%)	6 / 12 (50.00%)
occurrences (all)	3	5	7
ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	1 / 12 (8.33%)
occurrences (all)	0	3	1
ODYNOPHAGIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
PROCTALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CHOLECYSTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

OCULAR ICTERUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ECCHYMOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	2 / 12 (16.67%)
occurrences (all)	0	2	5
SKIN LESION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
DRUG ERUPTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	1 / 4 (25.00%)	3 / 7 (42.86%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
PURPURA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
SKIN DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	3
MUCOCUTANEOUS HAEMORRHAGE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
BLOOD BLISTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
HYPERHIDROSIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
RASH ERYTHEMATOUS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
SKIN EXFOLIATION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
ERYTHEMA NODOSUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Renal and urinary disorders			
MICTURITION FREQUENCY DECREASED			

subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
HAEMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
INCONTINENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COSTOVERTEBRAL ANGLE TENDERNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
NECK PAIN			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
MUSCLE FATIGUE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
ARTHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
MYOSITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
CHONDROCALCINOSIS PYROPHOSPHATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HAEMARTHROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ARTHRALGIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	2
MYALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHIOLITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CRYPTOCOCCOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FUNGAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
RECTAL ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CORONAVIRUS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
LIVER ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
RASH PUSTULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SYSTEMIC CANDIDA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA FUNGAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
PSEUDOMONAL BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
BETA HAEMOLYTIC STREPTOCOCCAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
ANORECTAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
WOUND INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
TRICHOSPORON INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PARAINFLUENZA (URI)			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
HYPOKALAEMIA			

subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	4 / 12 (33.33%)
occurrences (all)	1	1	9
DECREASED APPETITE			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	2 / 12 (16.67%)
occurrences (all)	1	2	2
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	2 / 12 (16.67%)
occurrences (all)	0	2	2
IRON OVERLOAD			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
FLUID RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
MALNUTRITION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
HYPERPHOSPHATAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	1 / 12 (8.33%)
occurrences (all)	1	2	1
HYPERMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
HYPOMAGNESAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	3 / 7 (42.86%)	1 / 12 (8.33%)
occurrences (all)	0	3	1
FLUID OVERLOAD			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPERVOLAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FOLATE DEFICIENCY			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
VITAMIN B12 DEFICIENCY			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Dose Escalation: Arm A (Venetoclax 400mg + Cobi 60mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 600mg + Ida 150mg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	6 / 6 (100.00%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEOPLASM			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LEUKAEMIA CUTIS			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
MONOCLONAL GAMMOPATHY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
THROMBOPHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FLUSHING			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HAEMATOMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
PHLEBITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
General disorders and administration site conditions			

CHILLS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	4 / 13 (30.77%)
occurrences (all)	0	0	7
PYREXIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	4 / 13 (30.77%)
occurrences (all)	1	0	6
FATIGUE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	4 / 13 (30.77%)
occurrences (all)	4	0	5
CYST			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
LOCALISED OEDEMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
FACIAL PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
GENERALISED OEDEMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
SUPRAPUBIC PAIN			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

MEDICAL DEVICE PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
ASTHENIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	4 / 13 (30.77%)
occurrences (all)	1	0	4
CHEST PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	4 / 7 (57.14%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	4	0	3
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
GENITAL LESION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
PELVIC PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PROSTATITIS			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
SCROTAL OEDEMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

PRODUCTIVE COUGH			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
THROAT IRRITATION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	4 / 13 (30.77%)
occurrences (all)	0	0	5
RALES			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	4
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HYPOXIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
RHINORRHOEA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TACHYPNOEA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
RHONCHI			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
EPISTAXIS			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
THROAT TIGHTNESS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	3 / 13 (23.08%)
occurrences (all)	0	1	4
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
PULMONARY VASCULAR DISORDER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PULMONARY OEDEMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HAEMOPTYSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DYSPHONIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PLEURITIC PAIN			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
PULMONARY MASS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
RESPIRATORY FAILURE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
CONFUSIONAL STATE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
DELIRIUM			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
ANXIETY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	4 / 13 (30.77%)
occurrences (all)	0	0	4
Investigations			
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	3
PROTHROMBIN TIME PROLONGED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ANTITHROMBIN III DECREASED			

subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	2
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	3
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
BREATH SOUNDS ABNORMAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
TROPONIN I INCREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
WEIGHT DECREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	3
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	2
CARDIAC MURMUR			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SERUM FERRITIN INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	4
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
BLOOD LACTIC ACID INCREASED			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	2
WEIGHT INCREASED			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
EJECTION FRACTION DECREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	2 / 13 (15.38%)
occurrences (all)	1	1	2
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
TROPONIN INCREASED			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BLOOD CHLORIDE INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	3
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
TRANSFUSION REACTION			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
PERIORBITAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKIN LACERATION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
POST PROCEDURAL ERYTHEMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
FALL			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
POST PROCEDURAL FEVER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
CONTUSION			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Cardiac disorders			
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
TACHYCARDIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BRADYCARDIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SINUS BRADYCARDIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
CARDIAC FAILURE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
TRANSIENT APHASIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LETHARGY			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
DYSGEUSIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	1	0	3
HEMIPARESIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	3
DIABETIC NEUROPATHY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
PRESYNCOPE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
HYPOGEUSIA			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
COAGULOPATHY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BONE MARROW FAILURE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
NEUTROPENIA			
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	4 / 13 (30.77%)
occurrences (all)	1	2	5
ANAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	6
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	4
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	3 / 13 (23.08%)
occurrences (all)	0	1	10
LEUKOPENIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
LYMPH NODE PAIN			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
SPLENOMEGALY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
LEUKOCYTOSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
EAR CONGESTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VITREOUS HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MACULAR OEDEMA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DIABETIC RETINOPATHY			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ORBITAL OEDEMA			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RETINAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VITREOUS DETACHMENT			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
DRY EYE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
RETINAL DRUSEN			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
OPTIC DISC DISORDER			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
NORMAL TENSION GLAUCOMA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
BLEPHARITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CATARACT			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
MELAENA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
CONSTIPATION			
subjects affected / exposed	2 / 7 (28.57%)	2 / 6 (33.33%)	4 / 13 (30.77%)
occurrences (all)	3	2	5

VOMITING			
subjects affected / exposed	5 / 7 (71.43%)	2 / 6 (33.33%)	7 / 13 (53.85%)
occurrences (all)	11	5	13
HAEMATOCHEZIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TONGUE DISCOLOURATION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
DRY MOUTH			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
ILEUS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
HAEMORRHOIDS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	4
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
COLITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	6 / 7 (85.71%)	6 / 6 (100.00%)	12 / 13 (92.31%)
occurrences (all)	15	15	26

ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	2
ANAL INCONTINENCE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
DYSPHAGIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
GINGIVAL PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	2
GINGIVAL HYPERTROPHY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
ORAL PAIN			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
DIVERTICULUM			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
DIVERTICULUM GASTRIC			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
LIP BLISTER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	6 / 7 (85.71%)	5 / 6 (83.33%)	11 / 13 (84.62%)
occurrences (all)	9	9	18
ABDOMINAL PAIN			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	2	0	4
ODYNOPHAGIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PROCTALGIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
DYSPEPSIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CHOLECYSTITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
OCULAR ICTERUS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
ECCHYMOSIS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
RASH			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
SKIN LESION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
DRUG ERUPTION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
PRURITUS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
PURPURA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKIN DISORDER			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
MUCOCUTANEOUS HAEMORRHAGE			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
DRY SKIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	4
BLOOD BLISTER			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HYPERHIDROSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SKIN EXFOLIATION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
ERYTHEMA NODOSUM			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
URTICARIA			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
MICTURITION FREQUENCY DECREASED			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ACUTE KIDNEY INJURY			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	2
HAEMATURIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
INCONTINENCE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
COSTOVERTEBRAL ANGLE TENDERNESS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
POLLAKIURIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
URINARY RETENTION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
NECK PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUSCLE FATIGUE			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ARTHRITIS			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MYOSITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
MUSCLE SPASMS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
CHONDROCALCINOSIS PYROPHOSPHATE			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
BACK PAIN			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	1	0	3
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HAEMARTHROSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
ARTHRALGIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	3	0	2
MYALGIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2

Infections and infestations			
BRONCHIOLITIS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
CRYPTOCOCCOSIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
FUNGAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RECTAL ABSCESS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HERPES VIRUS INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
ORAL HERPES			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
CORONAVIRUS INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
LIVER ABSCESS			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
GASTROINTESTINAL CANDIDIASIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
CATHETER SITE CELLULITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
SYSTEMIC CANDIDA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
CONJUNCTIVITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA FUNGAL			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
PNEUMONIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
PSEUDOMONAL BACTERAEMIA			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
BETA HAEMOLYTIC STREPTOCOCCAL INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
LARYNGITIS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ANORECTAL INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
WOUND INFECTION			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
TRICHOSPORON INFECTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
PARAINFLUENZA (URI)			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
HYPERGLYCAEMIA			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
HYPOKALAEMIA			
subjects affected / exposed	3 / 7 (42.86%)	4 / 6 (66.67%)	6 / 13 (46.15%)
occurrences (all)	5	4	11
DECREASED APPETITE			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	4 / 13 (30.77%)
occurrences (all)	3	2	4
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
HYPERKALAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
HYPOCALCAEMIA			
subjects affected / exposed	3 / 7 (42.86%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	3	1	1
IRON OVERLOAD			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
HYPONATRAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	2
HYPERPHOSPHATAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	2 / 13 (15.38%)
occurrences (all)	1	2	2
HYPERMAGNESAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
DEHYDRATION			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	3 / 13 (23.08%)
occurrences (all)	5	3	4
FLUID OVERLOAD			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
HYPOALBUMINAEMIA			
subjects affected / exposed	4 / 7 (57.14%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	7	0	0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
HYPERURICAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
HYPERVOLAEMIA			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FOLATE DEFICIENCY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOVOLAEMIA			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
VITAMIN B12 DEFICIENCY			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Escalation: Arm B (Venetoclax 600mg + Ida 200mg)	Dose Escalation: Arm B (Venetoclax 400mg + Ida 400mg)	Dose Optimisation: Arm B (Ven 600mg (Day 1 to 21) + Ida 150mg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)	9 / 9 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

NEOPLASM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LEUKAEMIA CUTIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MONOCLONAL GAMMOPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
THROMBOPHLEBITIS SUPERFICIAL			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
FLUSHING			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HAEMATOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PHLEBITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPOTENSION			
subjects affected / exposed	4 / 21 (19.05%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	5	2	0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	3 / 21 (14.29%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	4	2	0
PYREXIA			
subjects affected / exposed	3 / 21 (14.29%)	3 / 9 (33.33%)	1 / 6 (16.67%)
occurrences (all)	3	3	2
FATIGUE			
subjects affected / exposed	8 / 21 (38.10%)	1 / 9 (11.11%)	1 / 6 (16.67%)
occurrences (all)	10	1	1
CYST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
MALAISE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LOCALISED OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
FACIAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PAIN			

subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
SUPRAPUBIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MEDICAL DEVICE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ASTHENIA			
subjects affected / exposed	2 / 21 (9.52%)	5 / 9 (55.56%)	2 / 6 (33.33%)
occurrences (all)	2	8	2
CHEST PAIN			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	7 / 21 (33.33%)	3 / 9 (33.33%)	0 / 6 (0.00%)
occurrences (all)	7	4	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
GENITAL LESION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PROSTATITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VAGINAL HAEMORRHAGE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SCROTAL OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
THROAT IRRITATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	4 / 21 (19.05%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	4	2	0
RALES			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
LOWER RESPIRATORY TRACT CONGESTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
RHINORRHOEA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
TACHYPNOEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			

subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
RHONCHI			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	3 / 21 (14.29%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
THROAT TIGHTNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	5 / 21 (23.81%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	6	0	0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PULMONARY VASCULAR DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PULMONARY OEDEMA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HAEMOPTYSIS			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
HICCUPS			

subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
DYSPHONIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PULMONARY MASS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	3 / 21 (14.29%)	1 / 9 (11.11%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
CONFUSIONAL STATE			
subjects affected / exposed	3 / 21 (14.29%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
DELIRIUM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Investigations			
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	3 / 21 (14.29%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
PROTHROMBIN TIME PROLONGED			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ANTITHROMBIN III DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	5 / 21 (23.81%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	5	2	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BREATH SOUNDS ABNORMAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TROPONIN I INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	2 / 21 (9.52%)	2 / 9 (22.22%)	1 / 6 (16.67%)
occurrences (all)	2	2	1
PLATELET COUNT DECREASED			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
CARDIAC MURMUR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SERUM FERRITIN INCREASED			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD PHOSPHORUS INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
BLOOD LACTIC ACID INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	4 / 21 (19.05%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	4	2	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EJECTION FRACTION DECREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 21 (9.52%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TROPONIN INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
BLOOD CHLORIDE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	2 / 21 (9.52%)	1 / 9 (11.11%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
TRANSFUSION REACTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PERIORBITAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
SKIN LACERATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
POST PROCEDURAL FEVER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cardiac disorders			
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
TACHYCARDIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 21 (0.00%)	3 / 9 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
BRADYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
SINUS BRADYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CARDIAC FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Nervous system disorders			
TRANSIENT APHASIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
SOMNOLENCE			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
DIZZINESS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
HEMIPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
RESTLESS LEGS SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	5 / 21 (23.81%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	5	1	0
DIABETIC NEUROPATHY			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOGEUSIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
COAGULOPATHY			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
BONE MARROW FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	5 / 21 (23.81%)	3 / 9 (33.33%)	3 / 6 (50.00%)
occurrences (all)	7	6	7
ANAEMIA			
subjects affected / exposed	8 / 21 (38.10%)	1 / 9 (11.11%)	3 / 6 (50.00%)
occurrences (all)	8	1	3
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
FEBRILE NEUTROPENIA			
subjects affected / exposed	4 / 21 (19.05%)	2 / 9 (22.22%)	1 / 6 (16.67%)
occurrences (all)	5	2	1
THROMBOCYTOPENIA			

subjects affected / exposed	7 / 21 (33.33%)	3 / 9 (33.33%)	3 / 6 (50.00%)
occurrences (all)	7	5	4
LEUKOPENIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
LYMPH NODE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SPLENOMEGALY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
EAR CONGESTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VITREOUS HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MACULAR OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL SWELLING			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DIABETIC RETINOPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ORBITAL OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RETINAL HAEMORRHAGE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
VITREOUS DETACHMENT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RETINAL DRUSEN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
OPTIC DISC DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NORMAL TENSION GLAUCOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLEPHARITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CATARACT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

MELAENA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	4 / 21 (19.05%)	1 / 9 (11.11%)	2 / 6 (33.33%)
occurrences (all)	4	1	3
VOMITING			
subjects affected / exposed	14 / 21 (66.67%)	3 / 9 (33.33%)	3 / 6 (50.00%)
occurrences (all)	25	3	4
HAEMATOCHEZIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TONGUE DISCOLOURATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	3 / 21 (14.29%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
ILEUS			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
HAEMORRHOIDAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

COLITIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
DIARRHOEA			
subjects affected / exposed	18 / 21 (85.71%)	8 / 9 (88.89%)	4 / 6 (66.67%)
occurrences (all)	44	15	6
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
ANAL INCONTINENCE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GINGIVAL PAIN			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
MOUTH HAEMORRHAGE			
subjects affected / exposed	2 / 21 (9.52%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
FLATULENCE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
GINGIVAL HYPERTROPHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ORAL PAIN			

subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
DIVERTICULUM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
DIVERTICULUM GASTRIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GINGIVAL BLEEDING			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
TOOTHACHE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LIP BLISTER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	16 / 21 (76.19%)	6 / 9 (66.67%)	3 / 6 (50.00%)
occurrences (all)	31	9	6
ABDOMINAL PAIN			
subjects affected / exposed	4 / 21 (19.05%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	6	1	0
ODYNOPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			

subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
CHOLECYSTITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	2 / 21 (9.52%)	2 / 9 (22.22%)	1 / 6 (16.67%)
occurrences (all)	2	2	2
Skin and subcutaneous tissue disorders			
ECCHYMOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DRUG ERUPTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
PURPURA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SKIN DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
MUCOCUTANEOUS HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
BLOOD BLISTER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
NIGHT SWEATS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
PETECHIAE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DECUBITUS ULCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SKIN EXFOLIATION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA NODOSUM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
MICTURITION FREQUENCY DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
HAEMATURIA			
subjects affected / exposed	2 / 21 (9.52%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
INCONTINENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COSTOVERTEBRAL ANGLE TENDERNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

NECK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCLE FATIGUE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ARTHRITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MYOSITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
JOINT SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 21 (4.76%)	2 / 9 (22.22%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
CHONDROCALCINOSIS PYROPHOSPHATE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMARTHROSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ARTHRALGIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
MYALGIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 9 (11.11%)	2 / 6 (33.33%)
occurrences (all)	1	1	2
Infections and infestations			
BRONCHIOLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CRYPTOCOCCOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FUNGAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RECTAL ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
INFLUENZA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HERPES VIRUS INFECTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

CORONAVIRUS INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 21 (9.52%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
LIVER ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL CANDIDIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CATHETER SITE CELLULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
SYSTEMIC CANDIDA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0

PNEUMONIA FUNGAL			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
PSEUDOMONAL BACTERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
BETA HAEMOLYTIC STREPTOCOCCAL INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ANORECTAL INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WOUND INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TRICHOSPORON INFECTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PARAINFLUENZA (URI)			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	3 / 9 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	5	0
HYPOKALAEMIA			
subjects affected / exposed	10 / 21 (47.62%)	3 / 9 (33.33%)	5 / 6 (83.33%)
occurrences (all)	12	3	6
DECREASED APPETITE			
subjects affected / exposed	7 / 21 (33.33%)	3 / 9 (33.33%)	2 / 6 (33.33%)
occurrences (all)	9	3	2
HYPOPHOSPHATAEMIA			
subjects affected / exposed	6 / 21 (28.57%)	2 / 9 (22.22%)	2 / 6 (33.33%)
occurrences (all)	8	2	2
HYPERKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	3 / 21 (14.29%)	2 / 9 (22.22%)	2 / 6 (33.33%)
occurrences (all)	3	3	2
IRON OVERLOAD			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MALNUTRITION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	2 / 21 (9.52%)	1 / 9 (11.11%)	2 / 6 (33.33%)
occurrences (all)	2	1	2

HYPERPHOSPHATAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HYPERMAGNESAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
DEHYDRATION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	7 / 21 (33.33%)	2 / 9 (22.22%)	2 / 6 (33.33%)
occurrences (all)	9	2	2
FLUID OVERLOAD			
subjects affected / exposed	3 / 21 (14.29%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	3 / 21 (14.29%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPERVOLAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 9 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
FOLATE DEFICIENCY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOVOLAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VITAMIN B12 DEFICIENCY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 9 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 June 2016	Following updates were made: [1] Updates to Inclusion/Exclusion Criteria; [2] Updates to Dose Limiting Toxicity (DLT) Criteria; [3] Modification of Stratification factors used in the randomized portion of the study and [4] Addition of guidelines for the use of venetoclax and cobimetinib when co-administered with moderate CYP3A inhibitors.
23 November 2016	Following updates were made: [1] Updates to guidelines for administration of venetoclax with cobimetinib and venetoclax with idasanutlin; [2] Extension of interval for subject consent to 30 days from 21 days to allow subjects time to conduct all required assessments; [3] Updates to sample list of prohibited and cautionary medications in accordance with the FDA's updated guidelines and [4] Updates to recommendations for prevention of tumor lysis syndrome (TLS).
31 July 2017	Following updates were made: [1] Addition of New Cohort to Arm B to explore a lower dose level of idasanutlin to obtain additional safety and tolerability data; [2] Modification of Phase 1b dose-escalation rules to a 3+3+3 design to further evaluate safety and tolerability in each dose cohort; [3] Updates to Eligibility Criteria; [4] Updates to guidelines for dose interruption and dose modification after clearance of leukemia from bone marrow; [5] Updates to the response criteria for DLT evaluation and [6] Guidance to minimize GI toxicity including instructions for mandatory prophylaxis and toxicity management were updated.
31 January 2020	Following updates were made: [1] Addition of new Secondary Efficacy Endpoints; [2] Additional detail provided to clarify the analysis of PRO and geriatric assessment data; [3] Phase II expansion portion of the study was removed; [4] A dosing schedule-optimization phase including additional cohorts in Arm B were added to optimize the venetoclax dosing schedule; [5] Eligibility criteria were amended to include objective criteria to define subjects who are not candidates for cytotoxic chemotherapy and [6] Further evaluation of Arm A would not continue.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported