Clinical trial results:
A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB057643 in Subjects With Advanced Malignancies

Summary

EudraCT number	2017-002641-29
Trial protocol	FR
Global end of trial date	13 February 2019

Results information

Result version number	v1 (current)
This version publication date	23 February 2020
First version publication date	23 February 2020

Trial information

Trial identification

Sponsor protocol code	INCB57643-101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02711137
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cut-Off, Delaware, United States, 19803
Public contact	Incyte Corporation Call Centre, Incyte Corporation, +1 +80000027423, globalmedinfo@incyte.com
Scientific contact	Incyte Corporation Call Centre, Incyte Corporation, +1 +80000027423, globalmedinfo@incyte.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	01 May 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 February 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of INCB057643 as monotherapy and in combination with standard of care (SOC) agents in subjects with advanced malignancies.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 137
Worldwide total number of subjects	137
EEA total number of subjects	0

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)	61
From 65 to 84 years	76
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 137 subjects enrolled at 19 different sites in USA.

Pre-assignment

Screening details:

Subjects were assigned to either dose escalation/dose-expansion study of INCB057643 as monotherapy or in combination with SOC agents in subjects with relapsing or refractory malignancies.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part1/Treatment Group A : 8mg QD INCB057643

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB057643 monotherapy at the protocol specified starting dose in the TGA. Treatment Group A included solid tumors and lymphoma

Arm title	Part1/Treatment Group A : 12mg QD INCB057643

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB057643 monotherapy at the protocol specified starting dose in the TGA. Treatment Group A included solid tumors and lymphoma

Arm title	Part1/Treatment Group A : 16mg QD INCB057643

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB057643 monotherapy at the protocol specified starting dose in the TGA. Treatment Group A included solid tumors and lymphoma

Arm title	Part1/Treatment Group B : 8mg QD INCB057643
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy at the protocol-specified cohort escalation treatment group B (TGB), based on protocol-specific criteria. Treatment Group B included any acute leukemia, HR-MDS,MDS/MPN, or MF.

Arm title	Part1/Treatment Group B : 12mg QD INCB057643
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy at the protocol-specified cohort escalation treatment group B (TGB), based on protocol-specific criteria. Treatment Group B included any acute leukemia, HR-MDS,MDS/MPN, or MF.

Arm title	Part1/Treatment Group C : 8mg QD INCB057643
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy at the protocol-specified cohort escalation treatment group C (TGC), based on protocol-specific criteria. Treatment Group C includes subjects with MM

Arm title	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy at the specified RP2D dose selected in Part 1 cohort escalation treatment group A (TGA), based on protocol-specific criteria. Part 2 Treatment Group A expansion included pancreatic adenocarcinoma, castration-resistant prostrate cancer, breast cancer, high grade serious ovarian cancer, glioblastoma multiform, non-hodgkin's lymphoma, ewing's sarcoma, and solid tumor or lymphoma.

Arm title	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort
Arm description: -	
Arm type	Experimental

Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB057463 monotherapy at the specified RP2D dose selected in Part 1 cohort escalation treatment group B (TGB), based on protocol-specific criteria. Part 2 Treatment Group B expansion included pancreatic adenocarcinoma, castration-resistant prostrate cancer, breast cancer, high grade serious ovarian cancer, glioblastoma multiform, non-hodgkin's lymphoma, ewing's sarcoma, and solid tumor or lymphoma.

Arm title	Part3/Treatment Group A : 8 mg INCB057643 + Gemcitabine 1000mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB057643 monotherapy based on protocol-specific criteria. Part 3 will determine the MTD and/or a tolerated dose of the combination of INCB057643 and one of the SOC agents (Gemcitabine) in relapsed or refractory advanced or metastatic solid tumors and hematologic malignancies where Gemcitabine is relevant

Arm title	Part3/Treatment Group B : 8 mg INCB057643 + Paclitaxel 80mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy based on protocol-specific criteria. Part 3 will determine the MTD and/or a tolerated dose of the combination of INCB057643 and one of the SOC agents (Paclitaxel) in relapsed or refractory advanced or metastatic solid tumors and hematologic malignancies.

Arm title	Part3/Treatment Group C : 8 mg INCB057643 + Rucaparib 600mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy based on protocol-specific criteria. Part 3 will determine the MTD and/or a tolerated dose of the combination of INCB057643 and one of the SOC agents (Rucaparib) in relapsed or refractory advanced or metastatic solid tumors and hematologic malignancies.

Arm title	Part3/Treatment Group D : 8 mg INCB057643 + Abir +Predni

Arm description: -

Arm type	Experimental

Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy based on protocol-specific criteria. Part 3 will determine the MTD and/or a tolerated dose of the combination of INCB057643 and one of the SOC agents (Abiraterone + Prednisone) in Castration Resistant Prostrate Cancer .

Arm title	Part3/Treatment Group E : 8 mg INCB057643 + Ruxolitinib 20mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy based on protocol-specific criteria. Part 3 will determine the MTD and/or a tolerated dose of the combination of INCB057643 and one of the SOC agents (Ruxolitinib) in Myelofibrosis.

Arm title	Part3/Treatment Group F : 8 mg INCB057643 + Azacitidine 75mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	INCB057643
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Initial cohort dose of INCB054763 monotherapy based on protocol-specific criteria. Part 3 will determine the MTD and/or a tolerated dose of the combination of INCB057643 and one of the SOC agents (Azacitidine) in Acute Myeloid Leukemia and Myelodysplastic Syndrome

Arm title	Enrolled but not dosed

Arm description:

Subjects enrolled in the study but not dosed

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Part1/Treatment Group A : 8mg QD INCB057643	Part1/Treatment Group A : 12mg QD INCB057643	Part1/Treatment Group A : 16mg QD INCB057643
Started	4	5	8
Completed	0	0	0
Not completed	4	5	8
Physician decision	1	-	2
withdrawal by subject	1	-	-
Death	1	4	5

Unknown	-	1	-
study terminated by sponsor	-	-	1
Lost to follow-up	1	-	-

Number of subjects in period 1	Part1/Treatment Group B : 8mg QD INCB057643	Part1/Treatment Group B : 12mg QD INCB057643	Part1/Treatment Group C : 8mg QD INCB057643
Started	7	5	1
Completed	0	0	0
Not completed	7	5	1
Physician decision	1	1	-
withdrawal by subject	1	1	-
Death	5	3	1
Unknown	-	-	-
study terminated by sponsor	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort	Part3/Treatment Group A : 8 mg INCB057643 + Gemcitabine 1000mg
Started	86	5	1
Completed	0	0	0
Not completed	86	5	1
Physician decision	12	2	1
withdrawal by subject	7	-	-
Death	61	3	-
Unknown	3	-	-
study terminated by sponsor	1	-	-
Lost to follow-up	2	-	-

Number of subjects in period 1	Part3/Treatment Group B : 8 mg INCB057643 + Paclitaxel 80mg	Part3/Treatment Group C : 8 mg INCB057643 + Rucaparib 600mg	Part3/Treatment Group D : 8 mg INCB057643 + Abir +Predni
Started	2	4	3
Completed	0	0	0
Not completed	2	4	3
Physician decision	1	3	2
withdrawal by subject	-	-	-
Death	1	1	1
Unknown	-	-	-
study terminated by sponsor	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part3/Treatment Group E : 8 mg	Part3/Treatment Group F : 8 mg	Enrolled but not dosed

	INCB057643 + Ruxolitinib 20mg	INCB057643 + Azacitidine 75mg	
Started	1	2	3
Completed	0	0	0
Not completed	1	2	3
Physician decision	1	1	2
withdrawal by subject	-	1	-
Death	-	-	-
Unknown	-	-	1
study terminated by sponsor	-	-	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Part1/Treatment Group A : 8mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group A : 12mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group A : 16mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group B : 8mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group B : 12mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group C : 8mg QD INCB057643
Reporting group description: -	
Reporting group title	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort
Reporting group description: -	
Reporting group title	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort
Reporting group description: -	
Reporting group title	Part3/Treatment Group A : 8 mg INCB057643 + Gemcitabine 1000mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group B : 8 mg INCB057643 + Paclitaxel 80mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group C : 8 mg INCB057643 + Rucaparib 600mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group D : 8 mg INCB057643 + Abir +Predni
Reporting group description: -	
Reporting group title	Part3/Treatment Group E : 8 mg INCB057643 + Ruxolitinib 20mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group F : 8 mg INCB057643 + Azacitidine 75mg
Reporting group description: -	
Reporting group title	Enrolled but not dosed
Reporting group description:	
Subjects enrolled in the study but not dosed	

Reporting group values	Part1/Treatment Group A : 8mg QD INCB057643	Part1/Treatment Group A : 12mg QD INCB057643	Part1/Treatment Group A : 16mg QD INCB057643
Number of subjects	4	5	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	3	5
From 65-84 years	2	2	3
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	64.3	60.2	60.5
standard deviation	± 10.21	± 12.26	± 11.44
Gender categorical			
Units: Subjects			
Female	2	2	5
Male	2	3	3
Race			
Units: Subjects			
White/Caucasian	3	3	5
Black/African-American	1	0	2
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	1	0
Other	0	1	1
Missing	0	0	0

Reporting group values	Part1/Treatment Group B : 8mg QD INCB057643	Part1/Treatment Group B : 12mg QD INCB057643	Part1/Treatment Group C : 8mg QD INCB057643
Number of subjects	7	5	1
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)	2	0	0
From 65-84 years	5	5	1
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	68.9	75.8	70.0
standard deviation	± 5.81	± 7.33	± 0
Gender categorical			
Units: Subjects			
Female	3	1	0
Male	4	4	1
Race			
Units: Subjects			
White/Caucasian	6	4	0

Black/African-American	1	0	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Other	0	1	1
Missing	0	0	0

Reporting group values	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort	Part3/Treatment Group A : 8 mg INCB057643 + Gemcitabine 1000mg
Number of subjects	86	5	1
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)	44	1	0
From 65-84 years	42	4	1
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	60.6	72.6	72.0
standard deviation	± 13.80	± 10.92	± 0
Gender categorical Units: Subjects			
Female	48	0	1
Male	38	5	0
Race Units: Subjects			
White/Caucasian	72	5	0
Black/African-American	10	0	1
Asian	0	0	0
American-Indian/Alaska Native	1	0	0
Native Hawaiian/Pacific Islander	0	0	0
Other	2	0	0
Missing	1	0	0

Reporting group values	Part3/Treatment Group B : 8 mg INCB057643 + Paclitaxel 80mg	Part3/Treatment Group C : 8 mg INCB057643 + Rucaparib 600mg	Part3/Treatment Group D : 8 mg INCB057643 + Abir +Predni
Number of subjects	2	4	3
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	1
From 65-84 years	1	3	2
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	56.0	66.0	67.7
standard deviation	± 12.73	± 6.16	± 4.04
Gender categorical			
Units: Subjects			
Female	1	4	0
Male	1	0	3
Race			
Units: Subjects			
White/Caucasian	1	4	3
Black/African-American	1	0	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Other	0	0	0
Missing	0	0	0

Reporting group values	Part3/Treatment Group E : 8 mg INCB057643 + Ruxolitinib 20mg	Part3/Treatment Group F : 8 mg INCB057643 + Azacitidine 75mg	Enrolled but not dosed
Number of subjects	1	2	3
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	0	1
From 65-84 years	1	2	2
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	75.0	76.5	66.0
standard deviation	± 0	± 2.12	± 6.24
Gender categorical			
Units: Subjects			
Female	0	0	1
Male	1	2	2

Race Units: Subjects			
White/Caucasian	1	2	3
Black/African-American	0	0	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Other	0	0	0
Missing	0	0	0

Reporting group values	Total		
Number of subjects	137		
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)	61		
From 65-84 years	76		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	68		
Male	69		
Race Units: Subjects			
White/Caucasian	112		
Black/African-American	16		
Asian	0		
American-Indian/Alaska Native	1		
Native Hawaiian/Pacific Islander	1		
Other	6		
Missing	1		

End points

End points reporting groups

Reporting group title	Part1/Treatment Group A : 8mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group A : 12mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group A : 16mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group B : 8mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group B : 12mg QD INCB057643
Reporting group description: -	
Reporting group title	Part1/Treatment Group C : 8mg QD INCB057643
Reporting group description: -	
Reporting group title	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort
Reporting group description: -	
Reporting group title	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort
Reporting group description: -	
Reporting group title	Part3/Treatment Group A : 8 mg INCB057643 + Gemcitabine 1000mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group B : 8 mg INCB057643 + Paclitaxel 80mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group C : 8 mg INCB057643 + Rucaparib 600mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group D : 8 mg INCB057643 + Abir +Predni
Reporting group description: -	
Reporting group title	Part3/Treatment Group E : 8 mg INCB057643 + Ruxolitinib 20mg
Reporting group description: -	
Reporting group title	Part3/Treatment Group F : 8 mg INCB057643 + Azacitidine 75mg
Reporting group description: -	
Reporting group title	Enrolled but not dosed
Reporting group description:	
Subjects enrolled in the study but not dosed	
Subject analysis set title	Part 1 and 2 : 8mg QD INCB057643
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
PK Analysis was done on subjects by dosage irrelevant of the Part 1 or Part 2 assignment	
Subject analysis set title	Part 1 and 2 : 12 mg QD INCB057643
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
PK Analysis was done on subjects by dosage irrelevant of the Part 1 or Part 2 assignment	
Subject analysis set title	Part 1 and 2 : 16 mg QD INCB057643
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
PK Analysis was done on subjects by dosage irrelevant of the Part 1 or Part 2 assignment	

Primary: Safety and tolerability of INCB057643 as monotherapy and in combination with standard of care (SOC) agents in patients with advanced malignancies; assessed by clinical laboratory assessments, physical examinations, 12 lead ECGs, and adverse events (AEs)

End point title	Safety and tolerability of INCB057643 as monotherapy and in combination with standard of care (SOC) agents in patients with advanced malignancies; assessed by clinical laboratory assessments, physical examinations, 12 lead ECGs, and adverse events (AEs)[1]

End point description:

Descriptive statistics for clinical laboratory assessments, physical examinations, 12 lead ECGs are provided.
Tabulation of adverse events are provided.

End point type	Primary

End point timeframe:

From screening through at least 30 days after end of treatment, up to approximately 24 months

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: There is no hypothesis testing for this endpoint , descriptive analysis is provided.

End point values	Part1/Treatment Group A : 8mg QD INCB057643	Part1/Treatment Group A : 12mg QD INCB057643	Part1/Treatment Group A : 16mg QD INCB057643	Part1/Treatment Group B : 8mg QD INCB057643
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	7
Units: Subjects	4	5	8	7

End point values	Part1/Treatment Group B : 12mg QD INCB057643	Part1/Treatment Group C : 8mg QD INCB057643	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	1	86	5
Units: Subjects	5	1	86	5

End point values	Part3/Treatment Group A : 8 mg INCB057643 + Gemcitabine 1000mg	Part3/Treatment Group B : 8 mg INCB057643 + Paclitaxel 80mg	Part3/Treatment Group C : 8 mg INCB057643 + Rucaparib 600mg	Part3/Treatment Group D : 8 mg INCB057643 + Abir +Predni
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	4	3
Units: Subjects	1	2	4	3

End point values	Part3/Treatment Group E : 8 mg INCB057643 + Ruxolitinib 20mg	Part3/Treatment Group F : 8 mg INCB057643 + Azacitidine 75mg	Enrolled but not dosed	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	2	0[2]	
Units: Subjects	1	2		

Notes:

[2] - No Participants were treated

Statistical analyses

No statistical analyses for this end point

Secondary: AUC0-24 Analysis of INCB057643

End point title	AUC0-24 Analysis of INCB057643

End point description:

End point type	Secondary

End point timeframe:

AUC0-24 is the area under the plasma or serum concentration-time curve from time = 0 to the last measurable concentration at time = 24 measured at steady state (Day 8)

End point values	Part 1 and 2 : 8mg QD INCB057643	Part 1 and 2 : 12 mg QD INCB057643	Part 1 and 2 : 16 mg QD INCB057643	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	89	7	
Units: hours*nM				
geometric mean (geometric coefficient of variation)	1940 (± 45.1)	2740 (± 43.2)	3610 (± 71.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: T1/2: Terminal Half-life of INCB057643

End point title	T1/2: Terminal Half-life of INCB057643

End point description:

The apparent terminal half-life is the time required for plasma concentration to decrease by 50% after pseudo-equilibrium of distribution has been reached, and calculated as the natural logarithm of 2 (0.693) / Apparent terminal rate constant (λz).

End point type	Secondary

End point timeframe:

Day 8

End point values	Part 1 and 2 : 8mg QD INCB057643	Part 1 and 2 : 12 mg QD INCB057643	Part 1 and 2 : 16 mg QD INCB057643	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	89	7	
Units: hours				
geometric mean (geometric coefficient of variation)	9.67 (± 50.8)	9.17 (± 49.7)	12.8 (± 71.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: VzF: Apparent Volume of Distribution of INCB057643

End point title	VzF: Apparent Volume of Distribution of INCB057643

End point description:

End point type	Secondary

End point timeframe:

Apparent volume of distribution of INCB057643

End point values	Part 1 and 2 : 8mg QD INCB057643	Part 1 and 2 : 12 mg QD INCB057643	Part 1 and 2 : 16 mg QD INCB057643	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	89	7	
Units: Liters				
geometric mean (geometric coefficient of variation)	138 (± 46.1)	139 (± 51.2)	197 (± 42.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) With INCB057643 in Solid Tumors

End point title	Objective Response Rate (ORR) With INCB057643 in Solid Tumors[3]

End point description:

Objective response rate is defined as the proportion of subjects who have an objective response using the applicable disease assessment criteria.

End point type	Secondary

End point timeframe:

Efficacy measures from screening through end of treatment and follow-up (every 9 weeks), up to approximately 24 months

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ORR is summarized by tumor type.

End point values	Part1/Treatment Group A : 8mg QD INCB057643	Part1/Treatment Group A : 12mg QD INCB057643	Part1/Treatment Group A : 16mg QD INCB057643	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[4]	4[5]	6[6]	63[7]
Units: Subjects	0	0	0	0

Notes:

[4] - Efficacy Evaluable Population

[5] - Efficacy Evaluable Population

[6] - Efficacy Evaluable Population

[7] - Efficacy Evaluable Population

End point values	Part3/Treatment Group A : 8 mg INCB057643 + Gemcitabine 1000mg	Part3/Treatment Group B : 8 mg INCB057643 + Paclitaxel 80mg	Part3/Treatment Group C : 8 mg INCB057643 + Rucaparib 600mg	Part3/Treatment Group D : 8 mg INCB057643 + Abir +Predni
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[8]	2[9]	4[10]	3[11]
Units: Subjects	0	1	0	0

Notes:

[8] - Efficacy Evaluable Population

[9] - Efficacy Evaluable Population

[10] - Efficacy Evaluable Population

[11] - Efficacy Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax: Maximum Observed Plasma Concentration of INCB057643

End point title	Cmax: Maximum Observed Plasma Concentration of INCB057643

End point description:

End point type	Secondary

End point timeframe:

Predose, 0.5, 1, 2, 4, 6, 8 hours of C1D8

End point values	Part 1 and 2 : 8mg QD INCB057643	Part 1 and 2 : 12 mg QD INCB057643	Part 1 and 2 : 16 mg QD INCB057643	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	89	7	
Units: nM				
geometric mean (geometric coefficient of variation)	191 (± 50.3)	272 (± 40.9)	310 (± 47.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cmin: Minimum Observed Plasma Concentration Over the Dose Interval Analysis of INCB057643

End point title	Cmin: Minimum Observed Plasma Concentration Over the Dose Interval Analysis of INCB057643

End point description:

End point type	Secondary

End point timeframe:

Predose, 0.5, 1, 2, 4, 6, 8 hours of C1D8

End point values	Part 1 and 2 : 8mg QD INCB057643	Part 1 and 2 : 12 mg QD INCB057643	Part 1 and 2 : 16 mg QD INCB057643	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	89	7	
Units: nM				
geometric mean (geometric coefficient of variation)	27.1 (± 92.9)	39.1 (± 82.5)	63.7 (± 163)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cl/F Analysis of INCB0557643

End point title	Cl/F Analysis of INCB0557643

End point description:

End point type	Secondary

End point timeframe:

Predose,0.5, 1, 2, 4, 6, 8 hours of C1D8

End point values	Part 1 and 2 : 8mg QD INCB057643	Part 1 and 2 : 12 mg QD INCB057643	Part 1 and 2 : 16 mg QD INCB057643	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	89	7	
Units: Liters/Hour				
geometric mean (geometric coefficient of variation)	9.92 (± 45.1)	10.5 (± 43.2)	10.7 (± 71.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) With INCB057643 in Lymphoma

End point title	Objective Response Rate (ORR) With INCB057643 in Lymphoma[12]

End point description:

Objective response rate is defined as the proportion of subjects who have an objective response using the applicable disease assessment criteria.

End point type	Secondary

End point timeframe:

Efficacy measures from screening through end of treatment and follow-up (every 9 weeks), up to approximately 24 months

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ORR is summarized by tumor type.

End point values	Part1/Treatment Group A : 8mg QD INCB057643	Part1/Treatment Group A : 12mg QD INCB057643	Part1/Treatment Group A : 16mg QD INCB057643	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[13]	1[14]	2[15]	16[16]
Units: Subjects	1	0	1	2

Notes:

[13] - Efficacy Evaluable Population

[14] - Efficacy Evaluable Population

[15] - Efficacy Evaluable Population

[16] - Efficacy Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) With INCB057643 in Acute Myeloid

Leukemia

End point title	Objective Response Rate (ORR) With INCB057643 in Acute Myeloid Leukemia[17]

End point description:

Objective response rate is defined as the proportion of subjects who have an objective response using the applicable disease assessment criteria.

End point type	Secondary

End point timeframe:

Efficacy measures from screening through end of treatment and follow-up (every 9 weeks), up to approximately 24 months

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ORR is summarized by tumor type.

End point values	Part1/Treatment Group B : 8mg QD INCB057643	Part1/Treatment Group B : 12mg QD INCB057643	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort	Part3/Treatment Group F : 8 mg INCB057643 + Azacitidine 75mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[18]	2[19]	3[20]	2[21]
Units: Subjects	0	0	1	0

Notes:

[18] - Efficacy Evaluable Subjects

[19] - Efficacy Evaluable Subjects

[20] - Efficacy Evaluable Subjects

[21] - Efficacy Evaluable Subjects

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) With INCB057643 in Glioblastoma

End point title	Objective Response Rate (ORR) With INCB057643 in Glioblastoma[22]

End point description:

Objective response rate is defined as the proportion of subjects who have an objective response using the applicable disease assessment criteria.

End point type	Secondary

End point timeframe:

Efficacy measures from screening through end of treatment and follow-up (every 9 weeks), up to approximately 24 months

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ORR is summarized by tumor type.

End point values	Part2/Treatment Group A : 12 mg INCB057643 Expansion Cohort			
Subject group type	Reporting group			
Number of subjects analysed	7[23]			
Units: Subjects	0			

Notes:

[23] - Efficacy Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) With INCB057643 in Myelodysplastic Syndrome

End point title	Objective Response Rate (ORR) With INCB057643 in Myelodysplastic Syndrome[24]

End point description:

Objective response rate is defined as the proportion of subjects who have an objective response using the applicable disease assessment criteria.

End point type	Secondary

End point timeframe:

Efficacy measures from screening through end of treatment and follow-up (every 9 weeks), up to approximately 24 months

Notes:

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

Justification: ORR is summarized by tumor type.

End point values	Part1/Treatment Group B : 8mg QD INCB057643	Part1/Treatment Group B : 12mg QD INCB057643	Part2/Treatment Group B : 12 mg INCB057643 Expansion Cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1[25]	3[26]	1[27]	
Units: Subjects	0	0	0	

Notes:

[25] - Efficacy Evaluable Subjects

[26] - Efficacy Evaluable Subjects

[27] - Efficacy Evaluable Subjects

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From screening through at least 30 days after end of treatment, up to approximately 24 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19

Reporting groups	
Reporting group title	PART1A 8 MG QD
Reporting group description: PART1A 8 MG QD	
Reporting group title	PART1A 12 MG QD
Reporting group description: PART1A 12 MG QD	
Reporting group title	PART1A 16 MG QD
Reporting group description: PART1A 16 MG QD	
Reporting group title	PART1B 8 MG QD
Reporting group description: PART1B 8 MG QD	
Reporting group title	PART1B 12 MG QD
Reporting group description: PART1B 12 MG QD	
Reporting group title	PART1C 8 MG QD
Reporting group description: PART1C 8 MG QD	
Reporting group title	PART2A 12 MG QD
Reporting group description: PART2A 12 MG QD	
Reporting group title	PART2B 12 MG QD
Reporting group description: PART2B 12 MG QD	
Reporting group title	PART3A 8 MG QD + Gemcitabine 1000 MG/M2
Reporting group description: PART3A 8 MG QD + Gemcitabine 1000 MG/M2	
Reporting group title	PART3B 8 MG QD + Paci 80 MG/M2
Reporting group description: PART3B 8 MG QD + Paci 80 MG/M2	
Reporting group title	PART3C 8 MG QD + Rucap 600 MG
Reporting group description: PART3C 8 MG QD + Rucap 600 MG	
Reporting group title	PART3D 8 MG QD + Arbir 1000 MG + Predni 5 MG
Reporting group description: PART3D 8 MG QD + Arbir 1000 MG + Predni 5 MG	
Reporting group title	PART3E 8 MG QD + Rux 20 MG
Reporting group description: PART3E 8 MG QD + Rux 20 MG	
Reporting group title	PART3F 8 MG QD + Azacitadine 75 MG/M2

Serious adverse events	PART1A 8 MG QD	PART1A 12 MG QD	PART1A 16 MG QD
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	5 / 8 (62.50%)
number of deaths (all causes)	2	4	5
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Performance status decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
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 / 5 (0.00%)	0 / 8 (0.00%)
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 infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
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			
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontal disease			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
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	PART1B 8 MG QD	PART1B 12 MG QD	PART1C 8 MG QD
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	4 / 5 (80.00%)	1 / 1 (100.00%)
number of deaths (all causes)	6	4	1
number of deaths resulting from adverse events	3	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Performance status decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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 infiltration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Pulmonary embolism			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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

Pulmonary oedema			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Respiratory failure			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Investigations			
International normalised ratio increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (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
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Syncope			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontal disease			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Hepatic failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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	2 / 7 (28.57%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Nephrolithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (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
Pneumonia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	0 / 1 (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
Pneumonia bacterial			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (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

Serious adverse events	PART2A 12 MG QD	PART2B 12 MG QD	PART3A 8 MG QD + Gemcitabine 1000 MG/M2
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 86 (37.21%)	4 / 5 (80.00%)	0 / 1 (0.00%)
number of deaths (all causes)	68	3	0
number of deaths resulting from adverse events	12	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Performance status decreased			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (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
Lung infiltration			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (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
Pulmonary oedema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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	4 / 86 (4.65%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (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
Delirium			

subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
International normalised ratio increased			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (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 disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Syncope			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 86 (0.00%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (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
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (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
Periodontal disease			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (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
End stage renal disease			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (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	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	4 / 86 (4.65%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (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
Hyperglycaemia			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
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	PART3B 8 MG QD + Paci 80 MG/M2	PART3C 8 MG QD + Rucap 600 MG	PART3D 8 MG QD + Arbir 1000 MG + Predni 5 MG
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
number of deaths (all causes)	1	1	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Performance status decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontal disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Hepatic failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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	PART3E 8 MG QD + Rux 20 MG	PART3F 8 MG QD + Azacitadine 75 MG/M2	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Performance status decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontal disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

End stage renal disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Herpes zoster			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	PART1A 8 MG QD	PART1A 12 MG QD	PART1A 16 MG QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	5 / 5 (100.00%)	7 / 8 (87.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Hypotension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Catheter site erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Catheter site haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Drug withdrawal syndrome			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	4 / 5 (80.00%)	4 / 8 (50.00%)
occurrences (all)	2	4	4
Influenza like illness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Penile oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Wheezing			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Bilirubin conjugated increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Blood creatinine increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Platelet count decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	2	1	3
Weight increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Injury, poisoning and procedural complications			

Arthropod bite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Eye contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fractured sacrum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	3 / 8 (37.50%)
occurrences (all)	0	2	3
Febrile neutropenia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Splenic infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	6
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	2 / 8 (25.00%)
occurrences (all)	0	2	2
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	2 / 5 (40.00%)	3 / 8 (37.50%)
occurrences (all)	1	2	3
Dry mouth			

subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lip haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 4 (75.00%)	4 / 5 (80.00%)	4 / 8 (50.00%)
occurrences (all)	5	4	6
Oesophageal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 4 (50.00%)	2 / 5 (40.00%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			

subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	2	0	1
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Chancroid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1

Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymph gland infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Systemic candida			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			

subjects affected / exposed	3 / 4 (75.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	3	0	1
Viral infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 4 (50.00%)	2 / 5 (40.00%)	3 / 8 (37.50%)
occurrences (all)	2	2	3
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	3 / 8 (37.50%)
occurrences (all)	2	0	6
Hypertriglyceridaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	PART1B 8 MG QD	PART1B 12 MG QD	PART1C 8 MG QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	5 / 5 (100.00%)	0 / 1 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Benign neoplasm			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Catheter site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 7 (42.86%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	3	2	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Mucosal dryness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Mucosal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Oedema peripheral			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Penile oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 7 (14.29%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Dyspnoea			
subjects affected / exposed	2 / 7 (28.57%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	2 / 7 (28.57%)	4 / 5 (80.00%)	0 / 1 (0.00%)
occurrences (all)	2	9	0
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypoxia			

subjects affected / exposed	2 / 7 (28.57%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 7 (28.57%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pulmonary oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			

subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Platelet count decreased			
subjects affected / exposed	1 / 7 (14.29%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye contusion			

subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	2 / 7 (28.57%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Fractured sacrum			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	3 / 7 (42.86%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 7 (57.14%)	3 / 5 (60.00%)	0 / 1 (0.00%)
occurrences (all)	4	9	0
Febrile neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			

subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Splenic infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	5 / 7 (71.43%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	6	1	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			

subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Anal fissure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	4 / 7 (57.14%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	5	1	0
Dry mouth			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Lip haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 7 (42.86%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	3 / 7 (42.86%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Stomatitis			
subjects affected / exposed	2 / 7 (28.57%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	3	0
Vomiting			
subjects affected / exposed	3 / 7 (42.86%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Angioedema			

subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Purpura			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Rash			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Scab			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Acute sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chancroid			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Groin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Lung infection			
subjects affected / exposed	2 / 7 (28.57%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Lymph gland infection			

subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Systemic candida			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 7 (42.86%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	3	2	0

Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Hyperglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Metabolic acidosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PART2A 12 MG QD	PART2B 12 MG QD	PART3A 8 MG QD + Gemcitabine 1000 MG/M2
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	82 / 86 (95.35%)	5 / 5 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Hypertension			
subjects affected / exposed	3 / 86 (3.49%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Hypotension			
subjects affected / exposed	3 / 86 (3.49%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	3	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 86 (3.49%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Catheter site erythema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			

subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	36 / 86 (41.86%)	3 / 5 (60.00%)	0 / 1 (0.00%)
occurrences (all)	41	3	0
Influenza like illness			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	2 / 86 (2.33%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Performance status decreased			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	10 / 86 (11.63%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Reproductive system and breast			

disorders			
Penile oedema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	10 / 86 (11.63%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	12	2	0
Dyspnoea			
subjects affected / exposed	9 / 86 (10.47%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	9	1	0
Dyspnoea exertional			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	5 / 86 (5.81%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	5	1	0
Haemoptysis			
subjects affected / exposed	3 / 86 (3.49%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Hypoxia			
subjects affected / exposed	1 / 86 (1.16%)	3 / 5 (60.00%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Nasal congestion			
subjects affected / exposed	3 / 86 (3.49%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Oropharyngeal pain			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Pleural effusion			

subjects affected / exposed	6 / 86 (6.98%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	6	1	0
Pneumonitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Respiratory failure			
subjects affected / exposed	2 / 86 (2.33%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Sneezing			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Wheezing			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	3 / 86 (3.49%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Depression			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 86 (2.33%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Alanine aminotransferase increased			
subjects affected / exposed	7 / 86 (8.14%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 86 (8.14%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Bilirubin conjugated increased			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 86 (5.81%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Blood bilirubin increased			
subjects affected / exposed	10 / 86 (11.63%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
Blood creatinine increased			
subjects affected / exposed	5 / 86 (5.81%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Blood pressure increased			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	6 / 86 (6.98%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	8	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	8 / 86 (9.30%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Prothrombin time prolonged			

subjects affected / exposed	6 / 86 (6.98%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Troponin I increased			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Troponin increased			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	6 / 86 (6.98%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	6	1	0
Weight increased			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	5 / 86 (5.81%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	6 / 86 (6.98%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Eye contusion			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Fractured sacrum			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Laceration			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Transfusion reaction			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	4 / 86 (4.65%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	4	1	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	10 / 86 (11.63%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	12	2	0
Dysgeusia			

subjects affected / exposed	16 / 86 (18.60%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	16	1	0
Headache			
subjects affected / exposed	5 / 86 (5.81%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	15 / 86 (17.44%)	4 / 5 (80.00%)	0 / 1 (0.00%)
occurrences (all)	17	11	0
Febrile neutropenia			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Splenic infarction			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Splenomegaly			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	19 / 86 (22.09%)	3 / 5 (60.00%)	0 / 1 (0.00%)
occurrences (all)	26	3	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Vitreous floaters			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	3 / 86 (3.49%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	3	2	0
Abdominal pain upper			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Anal fissure			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	19 / 86 (22.09%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	19	1	0
Diarrhoea			
subjects affected / exposed	21 / 86 (24.42%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	25	1	0
Dry mouth			
subjects affected / exposed	8 / 86 (9.30%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Dyspepsia			
subjects affected / exposed	3 / 86 (3.49%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Flatulence			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lip haemorrhage			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	43 / 86 (50.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	47	1	0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Vomiting			
subjects affected / exposed	26 / 86 (30.23%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	35	1	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Alopecia			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Pain of skin			

subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 86 (0.00%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	4 / 86 (4.65%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	4	2	0
Purpura			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Scab			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	7 / 86 (8.14%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	8	1	0
Dysuria			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Urinary retention			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Back pain			
subjects affected / exposed	6 / 86 (6.98%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Flank pain			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Muscular weakness			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Musculoskeletal pain			
subjects affected / exposed	3 / 86 (3.49%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Neck pain			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Chancroid			

subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	5 / 86 (5.81%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymph gland infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	3 / 86 (3.49%)	2 / 5 (40.00%)	0 / 1 (0.00%)
occurrences (all)	3	2	0

Sinusitis			
subjects affected / exposed	2 / 86 (2.33%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Skin infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Staphylococcal infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Systemic candida			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 86 (1.16%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Urinary tract infection			
subjects affected / exposed	5 / 86 (5.81%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Viral infection			
subjects affected / exposed	1 / 86 (1.16%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	27 / 86 (31.40%)	3 / 5 (60.00%)	0 / 1 (0.00%)
occurrences (all)	28	3	0
Dehydration			
subjects affected / exposed	11 / 86 (12.79%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	15	0	0
Hyperglycaemia			
subjects affected / exposed	13 / 86 (15.12%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	15	0	0
Hypertriglyceridaemia			

subjects affected / exposed	2 / 86 (2.33%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	3 / 86 (3.49%)	1 / 5 (20.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Hypocalcaemia			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Hypokalaemia			
subjects affected / exposed	5 / 86 (5.81%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Hypomagnesaemia			
subjects affected / exposed	4 / 86 (4.65%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Hyponatraemia			
subjects affected / exposed	6 / 86 (6.98%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Hypophosphataemia			
subjects affected / exposed	9 / 86 (10.47%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	9	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 86 (0.00%)	0 / 5 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PART3B 8 MG QD + Paci 80 MG/M2	PART3C 8 MG QD + Rucap 600 MG	PART3D 8 MG QD + Arbir 1000 MG + Predni 5 MG
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	4 / 4 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	3 / 4 (75.00%)	0 / 3 (0.00%)
occurrences (all)	1	5	0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Performance status decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Penile oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vulvovaginal erythema			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Prothrombin time prolonged			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fractured sacrum			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	1 / 2 (50.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Splenic infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 2 (50.00%)	2 / 4 (50.00%)	1 / 3 (33.33%)
occurrences (all)	1	5	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	1 / 2 (50.00%)	3 / 4 (75.00%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	3 / 4 (75.00%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Angioedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Scab			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Chancroid			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymph gland infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Systemic candida			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	3 / 4 (75.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Metabolic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PART3E 8 MG QD + Rux 20 MG	PART3F 8 MG QD + Azacitadine 75 MG/M2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 2 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Benign neoplasm			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Catheter site erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Catheter site haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Catheter site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Drug withdrawal syndrome			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Mucosal dryness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Mucosal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Performance status decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Penile oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal erythema			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pneumonitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pulmonary oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sneezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Investigations			
Activated partial thromboplastin time prolonged			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Bilirubin conjugated increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood pressure increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Prothrombin time prolonged			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Troponin I increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Troponin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Weight increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Fractured sacrum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Laceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Transfusion reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Atrioventricular block second degree			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sinus bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ventricular arrhythmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Dysgeusia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Post herpetic neuralgia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Increased tendency to bruise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Lymph node pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	2	
Splenic infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Splenomegaly			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eyelid oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Retinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitreous floaters			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Anal fissure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	1 / 2 (50.00%)	
occurrences (all)	1	2	
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lip haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Nausea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Oesophageal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Angioedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pain of skin			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Purpura			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Scab			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pain in jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rotator cuff syndrome			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Chancroid			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Conjunctivitis				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Fungal infection				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Gingivitis				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Groin infection				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Herpes simplex				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Herpes zoster				
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)		
occurrences (all)	1	0		
Lower respiratory tract infection bacterial				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Lung infection				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Lymph gland infection				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Oral candidiasis				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Pneumonia				
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		

Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Staphylococcal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Systemic candida			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Hypertriglyceridaemia			

subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Metabolic acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported