



Clinical trial results:

A Phase 1/2 Open-Label, Dose Escalation Study Investigating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ASP2215 in Patients with Relapsed or Refractory Acute Myeloid Leukemia

Summary

EudraCT number	2014-002217-31
Trial protocol	DE IT FR
Global end of trial date	07 March 2018

Results information

Result version number	v1 (current)
This version publication date	22 March 2019
First version publication date	22 March 2019

Trial information

Trial identification

Sponsor protocol code	2215-CL-0101
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02014558
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Astellas Pharma Global Development, Inc.
Sponsor organisation address	1 Astellas Way, Northbrook, United States, 60062
Public contact	Clinical Trial Disclosure, Astellas Pharma Global Development, Inc., 1 8008887704, astellas.resultsdisclosure@astellas.com
Scientific contact	Clinical Trial Disclosure, Astellas Pharma Global Development, Inc., 1 8008887704, astellas.resultsdisclosure@astellas.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	07 March 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	07 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the study were to assess the safety and tolerability, including determination of the maximum tolerated dose (MTD) of oral gilteritinib in participants with relapsed or treatment-refractory acute myeloid leukemia (AML) and determine the pharmacokinetic parameters of gilteritinib.

Protection of trial subjects:

This clinical study was written, conducted and reported in accordance with the protocol, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, and applicable local regulations, including the European Directive 2001/20/EC, on the protection of human rights, and with the ethical principles that have their origin in the Declaration of Helsinki. Astellas ensures that the use and disclosure of protected health information (PHI) obtained during a research study complies with the federal, national and/or regional legislation related to the privacy and protection of personal information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 October 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	United States: 245
Worldwide total number of subjects	265
EEA total number of subjects	20

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	151
From 65 to 84 years	111
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

This dose-escalation/dose-expansion study was conducted in sites in the United States, Germany and Italy. The study had 7 dose-escalation cohorts with ≥ 3 participants enrolled at each dose level. Following escalation to the next dose cohort, additional participants were enrolled to the dose-expansion cohorts per protocol-specified criteria.

Pre-assignment

Screening details:

Participants with AML who relapsed after or were refractory to induction or salvage treatment were selected for this study. Re-enrollment into the dose-expansion cohorts was permissible for participants who discontinued treatment for reasons other than toxicity or disease progression, as long as they met the eligibility criteria.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Gilteritinib 20 mg in Escalation Phase

Arm description:

Participants received a single dose of 20 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 20 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day -2 and day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 40 mg in Escalation Phase
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Arm description:

Participants received a single dose of 40 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 40 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day -2 and day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after

dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 80 mg in Escalation Phase
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Arm description:

Participants received a single dose of 80 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 80 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day -2 and day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 120 mg in Escalation Phase
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Arm description:

Participants received a single dose of 120 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 120 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day -2 and day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 200 mg in Escalation Phase
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Arm description:

Participants received a single dose of 200 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 200 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day -2 and day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the

assigned treatment dosage.

Arm title	Gilteritinib 300 mg in Escalation Phase
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Arm description:

Participants received a single dose of 300 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 300 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day -2 and day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 450 mg in Escalation Phase
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Arm description:

Participants received a single dose of 450 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 450 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day -2 and day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 20 mg in Expansion Phase
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Arm description:

Participants received 20 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. Starting on day 16 of cycle 1, participants also received 200 mg voriconazole orally every 12 hours through day 1 of cycle 2.

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

Dosage and administration details:

Participants received 200 mg voriconazole tablets daily every 12 hours starting from day 16 of cycle 1 through day 1 of cycle 2.

Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 40 mg in Expansion Phase
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Arm description:

Participants received 40 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 80 mg in Expansion Phase
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Arm description:

Participants received 80 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Arm title	Gilteritinib 120 mg in Expansion Phase
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Arm description:

Participants received 120 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

assigned treatment dosage.

Arm title	Gilteritinib 200 mg in Expansion Phase
Arm description: Participants received 200 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, participants also received 500 mg cephalexin as a single oral dose.	
Arm type	Experimental
Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Investigational medicinal product name	Cephalexin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a single oral dose of 500 mg cephalexin tablet or capsule on day -1 and day 15 of cycle 1.

Arm title	Gilteritinib 300 mg in Expansion Phase
Arm description: Participants received 300 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, participants also received 2 mg midazolam as a single oral dose.	
Arm type	Experimental
Investigational medicinal product name	Midazolam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Syrup
Routes of administration	Oral use

Dosage and administration details:

Participants received a single oral dose of 2 mg midazolam syrup on day -1 and day 15 of cycle 1.

Investigational medicinal product name	Gilteritinib
Investigational medicinal product code	ASP2215
Other name	Xospata
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received gilteritinib orally once daily with water starting from day 1 of cycle 1, for continuous 28-day cycles. Food intake was restricted to at least 2 hours before and 1 hour after dosing. Gilteritinib was supplied in tablets of 10 mg, 40 mg and 100 mg and was given according to the assigned treatment dosage.

Number of subjects in period 1	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase
Started	5	3	3
Treated	5	3	3
Incorrect dose taken (should be 120 mg)	0	0	0
Re-enrolled	0	0	0
Completed	0	0	0
Not completed	5	3	3
Lack of Efficacy	1	2	1
Adverse Event	-	-	-
Death	1	-	-
Lost to Follow-up	-	-	-
Progressive Disease	1	-	1
Miscellaneous	2	1	1
Never Received Drug	-	-	-
Withdrawal by Patient	-	-	-

Number of subjects in period 1	Gilteritinib 120 mg in Escalation Phase	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase
Started	3	4	3
Treated	3	3	3
Incorrect dose taken (should be 120 mg)	0	0	0
Re-enrolled	0	0	0
Completed	0	0	0
Not completed	3	4	3
Lack of Efficacy	1	-	-
Adverse Event	-	1	-
Death	-	-	-
Lost to Follow-up	-	-	-
Progressive Disease	1	1	2
Miscellaneous	1	-	1
Never Received Drug	-	1	-
Withdrawal by Patient	-	1	-

Number of subjects in period 1	Gilteritinib 450 mg in Escalation Phase	Gilteritinib 20 mg in Expansion Phase	Gilteritinib 40 mg in Expansion Phase
Started	4	11	15
Treated	3	11	13
Incorrect dose taken (should be 120 mg)	0	1	0
Re-enrolled	0	0	0

Completed	0	0	0
Not completed	4	11	15
Lack of Efficacy	1	3	3
Adverse Event	-	-	2
Death	1	1	2
Lost to Follow-up	-	-	-
Progressive Disease	1	6	5
Miscellaneous	-	1	1
Never Received Drug	1	-	2
Withdrawal by Patient	-	-	-

Number of subjects in period 1	Gilteritinib 80 mg in Expansion Phase	Gilteritinib 120 mg in Expansion Phase	Gilteritinib 200 mg in Expansion Phase
Started	21	70	106
Treated	21	66	100
Incorrect dose taken (should be 120 mg)	0	0	0
Re-enrolled	0	1	4
Completed	0	0	0
Not completed	21	70	106
Lack of Efficacy	3	16	8
Adverse Event	2	5	22
Death	5	5	20
Lost to Follow-up	-	1	1
Progressive Disease	6	23	32
Miscellaneous	3	12	11
Never Received Drug	-	2	2
Withdrawal by Patient	2	6	10

Number of subjects in period 1	Gilteritinib 300 mg in Expansion Phase
Started	17
Treated	17
Incorrect dose taken (should be 120 mg)	0
Re-enrolled	0
Completed	0
Not completed	17
Lack of Efficacy	5
Adverse Event	3
Death	2
Lost to Follow-up	-
Progressive Disease	6
Miscellaneous	1

Never Received Drug	-
Withdrawal by Patient	-

Baseline characteristics

Reporting groups

Reporting group title	Gilteritinib 20 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 20 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 20 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 40 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 40 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 40 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 80 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 80 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 80 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 120 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 120 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 120 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 200 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 200 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 200 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 300 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 300 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 300 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 450 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 450 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 450 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 20 mg in Expansion Phase
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Reporting group description:

Participants received 20 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. Starting on day 16 of cycle 1, participants also received 200 mg voriconazole orally every 12 hours through day 1 of cycle 2.

Reporting group title	Gilteritinib 40 mg in Expansion Phase
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Reporting group description:

Participants received 40 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Reporting group title	Gilteritinib 80 mg in Expansion Phase
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Reporting group description:

Participants received 80 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-

day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Reporting group title	Gilteritinib 120 mg in Expansion Phase
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Reporting group description:

Participants received 120 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Reporting group title	Gilteritinib 200 mg in Expansion Phase
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Reporting group description:

Participants received 200 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, participants also received 500 mg cephalexin as a single oral dose.

Reporting group title	Gilteritinib 300 mg in Expansion Phase
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Reporting group description:

Participants received 300 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, participants also received 2 mg midazolam as a single oral dose.

Reporting group values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase
Number of subjects	5	3	3
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	65.8	56.7	61.0
standard deviation	± 6.8	± 6.7	± 8.7
Gender categorical			
Units: Subjects			
Male	3	2	2
Female	2	1	1
Race			
Units: Subjects			
White	5	2	3
Black or African American	0	0	0
Asian	0	1	0
Other	0	0	0
Ethnicity			
Units: Subjects			
Not Hispanic or Latino	5	3	2
Hispanic or latino	0	0	1
Local FLT3 Mutation Status			
Units: Subjects			
Negative	1	0	0
Positive	4	3	3
Duration of Disease (AML)			
The number of participants with available data for each arm are 4, 3, 2, 3, 2, 1, 3, 9, 11, 17, 48, 80, 15. SD could not be calculated for the 300 mg due to sample size of 1.			
Units: months			
arithmetic mean	19.7	10.81	62.46
standard deviation	± 24.62	± 8.58	± 6.97

Reporting group values	Gilteritinib 120 mg in Escalation Phase	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase
Number of subjects	3	4	3
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	61.7 ± 6.0	55.3 ± 17.5	55.3 ± 25.0
Gender categorical Units: Subjects			
Male	2	2	2
Femaile	1	2	1
Race Units: Subjects			
White	2	1	3
Black or African American	1	1	0
Asian	0	1	0
Other	0	1	0
Ethnicity Units: Subjects			
Not Hispanic or Latino	3	4	3
Hispanic or latino	0	0	0
Local FLT3 Mutation Status Units: Subjects			
Negative	1	2	1
Positive	2	2	2
Duration of Disease (AML)			
The number of participants with available data for each arm are 4, 3, 2, 3, 2, 1, 3, 9, 11,17, 48, 80, 15. SD could not be calculated for the 300 mg due to sample size of 1.			
Units: months arithmetic mean standard deviation	49.53 ± 72.17	9.46 ± 2.23	19.75 ± 99999

Reporting group values	Gilteritinib 450 mg in Escalation Phase	Gilteritinib 20 mg in Expansion Phase	Gilteritinib 40 mg in Expansion Phase
Number of subjects	4	11	15
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	59.3 ± 10.0	62.5 ± 11.4	54.6 ± 18.5
Gender categorical Units: Subjects			
Male	3	3	11
Femaile	1	8	4
Race Units: Subjects			
White	4	9	11

Black or African American	0	1	0
Asian	0	0	0
Other	0	1	4
Ethnicity Units: Subjects			
Not Hispanic or Latino	4	10	13
Hispanic or latino	0	1	2
Local FLT3 Mutation Status Units: Subjects			
Negative	1	1	8
Positive	3	10	7
Duration of Disease (AML)			
The number of participants with available data for each arm are 4, 3, 2, 3, 2, 1, 3, 9, 11,17, 48, 80, 15. SD could not be calculated for the 300 mg due to sample size of 1.			
Units: months			
arithmetic mean	7.21	11.79	10.53
standard deviation	± 4.27	± 6.82	± 11.22

Reporting group values	Gilteritinib 80 mg in Expansion Phase	Gilteritinib 120 mg in Expansion Phase	Gilteritinib 200 mg in Expansion Phase
Number of subjects	21	70	106
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	56.3	58.2	59.7
standard deviation	± 18.1	± 16.9	± 14.3
Gender categorical Units: Subjects			
Male	9	32	53
Femaile	12	38	53
Race Units: Subjects			
White	14	61	96
Black or African American	4	2	5
Asian	0	1	4
Other	3	6	1
Ethnicity Units: Subjects			
Not Hispanic or Latino	20	65	103
Hispanic or latino	1	5	3
Local FLT3 Mutation Status Units: Subjects			
Negative	12	13	11
Positive	9	57	95
Duration of Disease (AML)			
The number of participants with available data for each arm are 4, 3, 2, 3, 2, 1, 3, 9, 11,17, 48, 80, 15. SD could not be calculated for the 300 mg due to sample size of 1.			
Units: months			
arithmetic mean	16.3	12.43	11.04
standard deviation	± 9.85	± 11.13	± 9.86

Reporting group values	Gilteritinib 300 mg in Expansion Phase	Total	
Number of subjects	17	265	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	57.6 ± 15.9	-	
Gender categorical Units: Subjects			
Male	12	136	
Female	5	129	
Race Units: Subjects			
White	13	224	
Black or African American	3	17	
Asian	0	7	
Other	1	17	
Ethnicity Units: Subjects			
Not Hispanic or Latino	17	252	
Hispanic or Latino	0	13	
Local FLT3 Mutation Status Units: Subjects			
Negative	9	60	
Positive	8	205	
Duration of Disease (AML)			
The number of participants with available data for each arm are 4, 3, 2, 3, 2, 1, 3, 9, 11, 17, 48, 80, 15. SD could not be calculated for the 300 mg due to sample size of 1.			
Units: months arithmetic mean standard deviation	12.09 ± 17.76	-	

End points

End points reporting groups

Reporting group title	Gilteritinib 20 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 20 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 20 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 40 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 40 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 40 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 80 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 80 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 80 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 120 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 120 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 120 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 200 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 200 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 200 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 300 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 300 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 300 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 450 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 450 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 450 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 20 mg in Expansion Phase
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Reporting group description:

Participants received 20 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. Starting on day 16 of cycle 1, participants also received 200 mg voriconazole orally every 12 hours through day 1 of cycle 2.

Reporting group title	Gilteritinib 40 mg in Expansion Phase
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Reporting group description:

Participants received 40 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Reporting group title	Gilteritinib 80 mg in Expansion Phase
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Reporting group description:

Participants received 80 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-

day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Reporting group title	Gilteritinib 120 mg in Expansion Phase
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Reporting group description:

Participants received 120 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.

Reporting group title	Gilteritinib 200 mg in Expansion Phase
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Reporting group description:

Participants received 200 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, participants also received 500 mg cephalexin as a single oral dose.

Reporting group title	Gilteritinib 300 mg in Expansion Phase
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Reporting group description:

Participants received 300 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, participants also received 2 mg midazolam as a single oral dose.

Subject analysis set title	Gilteritinib 20 mg
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Subject analysis set type	Full analysis
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Subject analysis set description:

Participants received 20 mg gilteritinib orally once on day -2, and starting on day 1 of cycle 1, participants received 20 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation. This group is used for efficacy analysis.

Subject analysis set title	Gilteritinib 40 mg
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Subject analysis set type	Full analysis
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Subject analysis set description:

Participants received 40 mg gilteritinib orally once on day -2, and starting on day 1 of cycle 1, participants received 40 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation. This group is used for efficacy analysis.

Subject analysis set title	Gilteritinib 80 mg
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Subject analysis set type	Full analysis
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Subject analysis set description:

Participants received 80 mg gilteritinib orally once on day -2, and starting on day 1 of cycle 1, participants received 80 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation. This group is used for efficacy analysis.

Subject analysis set title	Gilteritinib 120 mg
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Subject analysis set type	Full analysis
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Subject analysis set description:

Participants received 120 mg gilteritinib orally once on day -2, and starting on day 1 of cycle 1, participants received 120 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation. This group is used for efficacy analysis.

Subject analysis set title	Gilteritinib 200 mg
----------------------------	---------------------

Subject analysis set type	Full analysis
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Subject analysis set description:

Participants received 200 mg gilteritinib orally once on day -2, and starting on day 1 of cycle 1, participants received 200 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation. This group is used for efficacy analysis.

Subject analysis set title	Gilteritinib 300 mg
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Subject analysis set type	Full analysis
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Subject analysis set description:

Participants received 300 mg gilteritinib orally once on day -2, and starting on day 1 of cycle 1, participants received 300 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation. This group is used for efficacy analysis.

Subject analysis set title	Gilteritinib 450 mg
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Subject analysis set type	Full analysis
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Subject analysis set description:

Participants received 450 mg gilteritinib orally once on day -2, and starting on day 1 of cycle 1, participants received 450 mg gilteritinib orally once daily in 28-day cycles until disease progression or

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

End point title	Number of Participants with Dose Limiting Toxicities (DLTs) ^[1]
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End point description:

To determine the maximum tolerated dose, safety was assessed by DLTs, defined as any grade ≥ 3 non-hematologic or extramedullary toxicity that occurred within 30 days starting with the first dose taken on day -2, and included the first treatment cycle in the dose escalation phase and in the first treatment cycle (28 days) in the dose expansion phase, that was considered to be possibly or probably related to study drug. Exceptions to this were the following: (1) Alopecia, anorexia or fatigue, (2) Grade 3 nausea and/or vomiting if not required tube feeding or total parenteral nutrition, or diarrhea if not required or prolonged hospitalization that was managed to grade ≤ 2 with standard antiemetic or antidiarrheal medications used at prescribed dose within 7 days of onset, (3) Grade 3 fever with neutropenia, with or without infection, (4) Grade 3 infection. Only evaluable participants (received at least 80% of intended dose or had DLT in cycle 1) in SAF were included in the analysis.

End point type	Primary
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End point timeframe:

From first dose up to end of cycle 1 (30 days)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There is no statistical analysis applicable for this endpoint.

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: Participants				
Any DLT	0	0	0	0
Blood and lymphatic system disorders	0	0	0	0
Cardiac disorders	0	0	0	0
Eye disorders	0	0	0	0
Gastrointestinal disorders	0	0	0	0
General disorders & administration site conditions	0	0	0	0
Hepatobiliary disorders	0	0	0	0
Infections and infestations	0	0	0	0
Investigations	0	0	0	0
Metabolism and nutrition disorders	0	0	0	0
Musculoskeletal and connective tissue disorders	0	0	0	0
Nervous system disorders	0	0	0	0
Renal and urinary disorders	0	0	0	0
Reproductive system and breast disorders	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	0	0
Vascular disorders	0	0	0	0

End point values	Gilteritinib 200 mg in	Gilteritinib 300 mg in	Gilteritinib 450 mg in	Gilteritinib 20 mg in
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	Escalation Phase	Escalation Phase	Escalation Phase	Expansion Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	9
Units: Participants				
Any DLT	0	0	2	1
Blood and lymphatic system disorders	0	0	0	0
Cardiac disorders	0	0	0	0
Eye disorders	0	0	0	0
Gastrointestinal disorders	0	0	1	0
General disorders & administration site conditions	0	0	0	0
Hepatobiliary disorders	0	0	0	0
Infections and infestations	0	0	0	0
Investigations	0	0	1	0
Metabolism and nutrition disorders	0	0	0	0
Musculoskeletal and connective tissue disorders	0	0	0	0
Nervous system disorders	0	0	0	1
Renal and urinary disorders	0	0	0	0
Reproductive system and breast disorders	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	0	0
Vascular disorders	0	0	0	0

End point values	Gilteritinib 40 mg in Expansion Phase	Gilteritinib 80 mg in Expansion Phase	Gilteritinib 120 mg in Expansion Phase	Gilteritinib 200 mg in Expansion Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	18	62	87
Units: Participants				
Any DLT	1	2	7	15
Blood and lymphatic system disorders	0	0	0	0
Cardiac disorders	0	0	1	0
Eye disorders	0	1	0	0
Gastrointestinal disorders	0	0	1	4
General disorders & administration site conditions	0	0	0	1
Hepatobiliary disorders	0	0	1	0
Infections and infestations	1	1	0	0
Investigations	0	0	2	6
Metabolism and nutrition disorders	0	0	0	2
Musculoskeletal and connective tissue disorders	0	0	0	1
Nervous system disorders	0	0	0	3
Renal and urinary disorders	0	0	1	0
Reproductive system and breast disorders	0	0	0	1
Respiratory, thoracic and mediastinal disorders	0	0	1	2
Vascular disorders	0	0	0	2

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Participants				
Any DLT	3			
Blood and lymphatic system disorders	1			
Cardiac disorders	0			
Eye disorders	0			
Gastrointestinal disorders	1			
General disorders & administration site conditions	0			
Hepatobiliary disorders	0			
Infections and infestations	0			
Investigations	2			
Metabolism and nutrition disorders	0			
Musculoskeletal and connective tissue disorders	1			
Nervous system disorders	0			
Renal and urinary disorders	0			
Reproductive system and breast disorders	0			
Respiratory, thoracic and mediastinal disorders	1			
Vascular disorders	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Adverse Events (AEs)

End point title	Number of Participants with Adverse Events (AEs) ^[2]
End point description:	
Safety was assessed by AEs, which included abnormalities identified during a medical test (e.g. laboratory tests, vital signs, electrocardiogram, etc) if the abnormality induced clinical signs or symptoms, needed active intervention, interruption or discontinuation of study medication or was clinically significant. A treatment-emergent AE (TEAE) was defined as an AE observed after starting administration of the study drug up to 30 days after last dose of study drug (for participants who underwent hematopoietic stem cell transplantation [HSCT]: defined as AEs observed after starting study drug until the last dose before on study HSCT plus 30 days, and AEs that began after resumption of gilteritinib and w/in 30 days after the last dose of gilteritinib). AEs were graded using the National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03 (1-Mild, 2-Moderate, 3-Severe, 4-LifeThreatening, 5-Death). The analysis population was the SAF (reflected actual treatment).	
End point type	Primary
End point timeframe:	
From first dose of study drug up to 30 days after last dose of study drug (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There is no statistical analysis applicable for this endpoint.

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	3	3
Units: Participants				
AEs	5	3	3	3
Drug-Related AEs	3	2	1	3
Deaths	2	2	0	1
Serious AEs	2	2	2	1
Drug-Related Serious AEs	0	0	0	1
AEs Leading to Discontinuation of Study Drug	2	0	1	0
Drug-Related AEs Leading to Discont. of Study Drug	0	0	0	0
Grade 3 or Higher TEAEs	3	2	2	1
AEs During On-Study HSCT Period	0	0	0	0
Serious AEs During On-Study HSCT	0	0	0	0

End point values	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase	Gilteritinib 450 mg in Escalation Phase	Gilteritinib 20 mg in Expansion Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	11 ^[3]
Units: Participants				
AEs	3	3	3	11
Drug-Related AEs	3	2	3	7
Deaths	1	1	1	3
Serious AEs	2	2	2	8
Drug-Related Serious AEs	1	0	2	2
AEs Leading to Discontinuation of Study Drug	1	0	1	2
Drug-Related AEs Leading to Discont. of Study Drug	0	0	0	1
Grade 3 or Higher TEAEs	2	2	3	9
AEs During On-Study HSCT Period	0	0	0	0
Serious AEs During On-Study HSCT	0	0	0	0

Notes:

[3] - Actual number of participants treated & analyzed is 12. Need to reflect 11 due to validation error.

End point values	Gilteritinib 40 mg in Expansion Phase	Gilteritinib 80 mg in Expansion Phase	Gilteritinib 120 mg in Expansion Phase	Gilteritinib 200 mg in Expansion Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	21	66	100

Units: Participants				
AEs	13	20	64	100
Drug-Related AEs	6	17	52	77
Deaths	4	11	23	49
Serious AEs	12	19	52	92
Drug-Related Serious AEs	1	10	19	36
AEs Leading to Discontinuation of Study Drug	5	11	12	46
Drug-Related AEs Leading to Discont. of Study Drug	1	4	5	10
Grade 3 or Higher TEAEs	13	20	59	99
AEs During On-Study HSCT Period	0	0	3	7
Serious AEs During On-Study HSCT	0	0	0	3

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Participants				
AEs	17			
Drug-Related AEs	13			
Deaths	7			
Serious AEs	14			
Drug-Related Serious AEs	4			
AEs Leading to Discontinuation of Study Drug	6			
Drug-Related AEs Leading to Discont. of Study Drug	3			
Grade 3 or Higher TEAEs	14			
AEs During On-Study HSCT Period	0			
Serious AEs During On-Study HSCT	0			

Statistical analyses

No statistical analyses for this end point

Primary: Area Under the Concentration-time Curve Over the 24-Hour Dosing Interval (AUC24) after Single and Multiple Doses of Gilteritinib

End point title	Area Under the Concentration-time Curve Over the 24-Hour Dosing Interval (AUC24) after Single and Multiple Doses of Gilteritinib ^[4]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the pharmacokinetics analysis set (PKAS), which consisted of the subset of the SAF for which sufficient plasma concentration data were available to facilitate derivation of at least 1 pharmacokinetic parameter and for whom the time of dosing on the day of sampling was known. N is the number of participants with available data (applies to all endpoints). Data that could not be calculated due to low number of participants with evaluable samples is denoted as "+/-99999."

End point type	Primary
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End point timeframe:

Day -2 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose

Notes:

[4] - 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: Only gilteritinib escalation groups are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	3	3
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Day -2 [N=5, 3, 3, 3, 3, 2]	302.1 (± 207.0)	360.0 (± 223.5)	1216 (± 472.6)	2480 (± 1972)
Cycle 1 day 15 [N=3, 2, 3, 3, 2, 3, 1]	1299 (± 1006)	2482 (± 33.28)	6958 (± 3273)	6943 (± 3221)

End point values	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase	Gilteritinib 450 mg in Escalation Phase	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	3	3	
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Day -2 [N=5, 3, 3, 3, 3, 2]	3022 (± 843.6)	4163 (± 3178)	3324 (± 221.1)	
Cycle 1 day 15 [N=3, 2, 3, 3, 2, 3, 1]	31428 (± 21412)	31005 (± 10068)	34768 (± 99999)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Dose Proportionality (Single Dose / Day -2) was evaluated using the power model.	
Comparison groups	Gilteritinib 450 mg in Escalation Phase v Gilteritinib 20 mg in Escalation Phase v Gilteritinib 300 mg in Escalation Phase v Gilteritinib 200 mg in Escalation Phase v Gilteritinib 120 mg in Escalation Phase v Gilteritinib 80 mg in Escalation Phase v Gilteritinib 40 mg in Escalation Phase
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Slope
Point estimate	0.99
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.788
upper limit	1.19

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Dose Proportionality (Multiple Dose / Cycle 1 Day 15) was evaluated using the power model.	
Comparison groups	Gilteritinib 450 mg in Escalation Phase v Gilteritinib 20 mg in Escalation Phase v Gilteritinib 300 mg in Escalation Phase v Gilteritinib 200 mg in Escalation Phase v Gilteritinib 120 mg in Escalation Phase v Gilteritinib 80 mg in Escalation Phase v Gilteritinib 40 mg in Escalation Phase
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Slope
Point estimate	1.22
Confidence interval	
level	90 %
sides	2-sided
lower limit	1
upper limit	1.43

Primary: Maximum Concentration (Cmax) after Single and Multiple Doses of Gilteritinib

End point title	Maximum Concentration (Cmax) after Single and Multiple Doses of Gilteritinib ^[5]
End point description: Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS. Data that could not be calculated due to low number of participants with evaluable samples is denoted as "+/-99999."	
End point type	Primary
End point timeframe: Day -2 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose	
Notes: [5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only gilteritinib escalation groups are applicable to this endpoint.	

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	3	3
Units: ng/mL				
arithmetic mean (standard deviation)				
Day -2 [N=5, 3, 3, 3, 3, 3]	28.13 (± 21.49)	24.98 (± 14.58)	75.29 (± 25.22)	136.7 (± 94.37)
Cycle 1 day 15 [N=4, 3, 3, 3, 2, 3, 1]	64.64 (± 48.77)	107.6 (± 31.92)	376.4 (± 150.5)	374.2 (± 190.1)

End point values	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase	Gilteritinib 450 mg in Escalation Phase	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	3	3	
Units: ng/mL				
arithmetic mean (standard deviation)				
Day -2 [N=5, 3, 3, 3, 3, 3]	168.2 (± 45.34)	204.3 (± 136.4)	207.6 (± 51.81)	
Cycle 1 day 15 [N=4, 3, 3, 3, 2, 3, 1]	1462 (± 815.1)	1525 (± 664.6)	1528 (± 99999)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Dose Proportionality (Single Dose / Day -2) was evaluated using the power model.	
Comparison groups	Gilteritinib 20 mg in Escalation Phase v Gilteritinib 450 mg in Escalation Phase v Gilteritinib 200 mg in Escalation Phase v Gilteritinib 300 mg in Escalation Phase v Gilteritinib 120 mg in Escalation Phase v Gilteritinib 80 mg in Escalation Phase v Gilteritinib 40 mg in Escalation Phase
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Slope
Point estimate	0.808
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.629
upper limit	0.988

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Dose Proportionality (Multiple Dose / Cycle 1 Day 15) was evaluated using the power model.	
Comparison groups	Gilteritinib 20 mg in Escalation Phase v Gilteritinib 450 mg in Escalation Phase v Gilteritinib 200 mg in Escalation Phase v Gilteritinib 300 mg in Escalation Phase v Gilteritinib 120 mg in Escalation Phase v Gilteritinib 80 mg in Escalation Phase v Gilteritinib 40 mg in Escalation Phase

Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Slope
Point estimate	1.21
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.02
upper limit	1.41

Primary: Area Under the Concentration-time Curve from the Time of Dosing to the Last Measurable Concentration (AUClast) after Single and Multiple Doses of Gilteritinib

End point title	Area Under the Concentration-time Curve from the Time of Dosing to the Last Measurable Concentration (AUClast) after Single and Multiple Doses of Gilteritinib ^{[6][7]}
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS. Data that could not be calculated due to low number of participants with evaluable samples is denoted as "+/-99999."

End point type	Primary
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End point timeframe:

Day -2 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose

Notes:

[6] - 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 statistical analysis applicable for this endpoint.

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

Justification: Only gilteitinib escalation groups are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	3	3
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Day -2 [N=5, 3, 3, 3, 3, 3, 3]	303.0 (± 207.1)	360.4 (± 224.1)	1216 (± 472.6)	2480 (± 1972)
Cycle 1 day 15 [N=4, 3, 3, 3, 2, 3, 1]	1030 (± 984.2)	1990 (± 1422)	7111 (± 3525)	6943 (± 3221)

End point values	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase	Gilteritinib 450 mg in Escalation Phase	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	3	3	
Units: ng*h/mL				

arithmetic mean (standard deviation)				
Day -2 [N=5, 3, 3, 3, 3, 3, 3]	3024 (\pm 846.2)	4181 (\pm 3189)	2544 (\pm 1427)	
Cycle 1 day 15 [N=4, 3, 3, 3, 2, 3, 1]	32248 (\pm 22571)	31749 (\pm 10090)	35506 (\pm 99999)	

Statistical analyses

No statistical analyses for this end point

Primary: Time to Observed Cmax (tmax) after Single and Multiple Doses of Gilteritinib

End point title	Time to Observed Cmax (tmax) after Single and Multiple Doses of Gilteritinib ^[8] ^[9]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS. Data that could not be calculated due to low number of participants with evaluable samples is denoted as "+/-99999."

End point type	Primary
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End point timeframe:

Day -2 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There is no statistical analysis applicable for this endpoint.

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

Justification: Only gilteritinib escalation groups are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	3	3
Units: hours				
median (full range (min-max))				
Day -2 [N=5, 3, 3, 3, 3, 3, 3]	2.00 (0.500 to 4.03)	5.983 (3.97 to 24.0)	4.000 (4.00 to 4.08)	2.083 (2.00 to 3.83)
Cycle 1 day 15 [N=4, 3, 3, 3, 2, 3, 1]	4.008 (4.00 to 6.00)	3.867 (0.50 to 6.00)	4.333 (4.00 to 4.42)	2.167 (1.95 to 5.75)

End point values	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase	Gilteritinib 450 mg in Escalation Phase	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	3	3	
Units: hours				
median (full range (min-max))				
Day -2 [N=5, 3, 3, 3, 3, 3, 3]	5.233 (4.00 to 5.97)	6.067 (4.08 to 24.1)	5.783 (4.08 to 5.92)	

Cycle 1 day 15 [N=4, 3, 3, 3, 2, 3, 1]	6.033 (6.00 to 6.07)	6.050 (4.08 to 6.07)	5.933 (-99999 to 99999)	
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Statistical analyses

No statistical analyses for this end point

Primary: Terminal Elimination Half-life (t_{1/2}) After Multiple Doses of Gilteritinib

End point title	Terminal Elimination Half-life (t _{1/2}) After Multiple Doses of Gilteritinib ^{[10][11]}
End point description:	Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS.
End point type	Primary
End point timeframe:	Cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose

Notes:

[10] - 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 statistical analysis applicable for this endpoint.

[11] - 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: Only gilteritinib escalation groups are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	3	3
Units: hours				
arithmetic mean (standard deviation)	62.14 (± 17.88)	151.8 (± 129.2)	86.11 (± 24.08)	45.85 (± 18.83)

End point values	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase	Gilteritinib 450 mg in Escalation Phase	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	3	0 ^[12]	
Units: hours				
arithmetic mean (standard deviation)	141.9 (± 61.51)	142.2 (± 55.04)	()	

Notes:

[12] - Data could not be calculated due to no evaluable samples.

Statistical analyses

No statistical analyses for this end point

Primary: Accumulation Ratio After Multiple Doses of Gilteritinib

End point title Accumulation Ratio After Multiple Doses of Gilteritinib^[13]^[14]

End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS.

End point type Primary

End point timeframe:

Cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose

Notes:

[13] - 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 statistical analysis applicable for this endpoint.

[14] - 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: Only gilteritinib escalation groups are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 80 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	3	3
Units: ratio				
arithmetic mean (standard deviation)	4.259 (± 1.069)	9.640 (± 7.754)	5.693 (± 1.442)	3.290 (± 1.118)

End point values	Gilteritinib 200 mg in Escalation Phase	Gilteritinib 300 mg in Escalation Phase	Gilteritinib 450 mg in Escalation Phase	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	3	0 ^[15]	
Units: ratio				
arithmetic mean (standard deviation)	9.041 (± 3.693)	9.057 (± 3.303)	()	

Notes:

[15] - Data could not be calculated due to no evaluable samples.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Remission (CR) During the First 2 Cycles

End point title Percentage of Participants with Complete Remission (CR) During the First 2 Cycles

End point description:

CR was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally evaluated bone marrow aspirate/biopsy assessments (derived response). Participants were in CR when

they had bone marrow regenerating normal hematopoietic cells, achieved a morphologic leukemia-free state, had an absolute neutrophil count (ANC) $> 1 \times 10^9/L$, platelet count $\geq 100 \times 10^9/L$, normal marrow differential with $< 5\%$ blasts, had been red blood cell (RBC) and platelet transfusion independent (defined as 1 week without RBC transfusion and 1 week without platelet transfusion), had no presence of Auer rods and no evidence of extramedullary leukemia, and blast counts in peripheral blood had been $\leq 2\%$. FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
End point timeframe:	
During the first 2 cycles (56 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	0 (-99999 to 99999)	0 (-99999 to 99999)	8.3 (0.2 to 38.5)	3.6 (0.4 to 12.3)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	50.0 (1.3 to 98.7)	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	6.3 (0.2 to 30.2)	0 (-99999 to 99999)	4.2 (0.1 to 21.1)	2.9 (0.3 to 9.9)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	3.4 (0.7 to 9.5)	10 (0.3 to 44.5)	0 (-99999 to 99999)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	3.0 (0.6 to 8.5)	5.0 (0.1 to 24.9)	0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR During Treatment

End point title	Percentage of Participants with CR During Treatment
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End point description:

CR was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally evaluated bone marrow aspirate/biopsy assessments (derived response). Participants were in CR when they had bone marrow regenerating normal hematopoietic cells, achieved a morphologic leukemia-free

state, had an absolute neutrophil count (ANC) > 1 x 10⁹/L, platelet count ≥ 100 x 10⁹/L, normal marrow differential with < 5% blasts, had been red blood cell (RBC) and platelet transfusion independent (defined as 1 week without RBC transfusion and 1 week without platelet transfusion), had no presence of Auer rods and no evidence of extramedullary leukemia, and blast counts in peripheral blood had been ≤ 2%. FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	0 (-99999 to 99999)	0 (-99999 to 99999)	16.7 (2.1 to 48.4)	12.5 (5.2 to 24.1)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	50.0 (1.3 to 98.7)	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	6.3 (0.2 to 30.2)	0 (-99999 to 99999)	8.3 (1.0 to 27.0)	10.0 (4.1 to 19.5)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	11.2 (5.5 to 19.7)	10.0 (0.3 to 44.5)	0 (-99999 to 99999)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	10.0 (4.9 to 17.6)	5.0 (0.1 to 24.9)	0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR with Incomplete Platelet Recovery (CRp)

End point title	Percentage of Participants with CR with Incomplete Platelet Recovery (CRp)
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End point description:

CRp was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally

evaluated bone marrow aspirate/biopsy assessments (derived response). Participants were in CRp when they achieved CR except for incomplete platelet recovery ($< 100 \times 10^9/L$). The analysis population was the full analysis set (FAS), which consisted of all participants who were enrolled, took at least 1 dose of study drug and who had at least 1 posttreatment data point. Re-enrolled participants and participants from one site due to concerns with this site's GCP compliance were excluded. Participants were summarized under planned reporting groups in the FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
End point timeframe:	
Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)	3.6 (0.4 to 12.3)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)	2.9 (0.3 to 9.9)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	9.0 (4.0 to 16.9)	10.0 (0.3 to 44.5)	0 (-99999 to 99999)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	8.0 (3.5 to 15.2)	5.0 (0.1 to 24.9)	0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with CR with Incomplete Hematological Recovery (CRi)

End point title	Percentage of Participants with CR with Incomplete Hematological Recovery (CRi)
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End point description:

CRi was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if

neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally evaluated bone marrow aspirate/biopsy assessments (derived response). Participants were in CRi when they fulfilled all the criteria for CR except for incomplete hematological recovery with residual neutropenia $< 1 \times 10^9/L$ with or without complete platelet recovery. RBC and platelet transfusion independence were not required. The analysis population was the FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	7.1 (0.2 to 33.9)	0 (-99999 to 99999)	25.0 (5.5 to 57.2)	30.4 (18.8 to 44.1)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	0 (-99999 to 99999)	0 (-99999 to 99999)	16.7 (2.1 to 48.4)	7.1 (0.2 to 33.9)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	6.3 (0.2 to 30.2)	0 (-99999 to 99999)	20.8 (7.1 to 42.2)	25.7 (16.0 to 37.6)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	20.2 (12.4 to 30.1)	10.0 (0.3 to 44.5)	0 (-99999 to 99999)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	9.1 (0.2 to 41.3)	0 (-99999 to 99999)	0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	19.0 (11.8 to 28.1)	5.0 (0.1 to 24.9)	0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Remission with Partial Hematologic Recovery (CRh)

End point title	Percentage of Participants with Complete Remission with Partial Hematologic Recovery (CRh)
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End point description:

CRh was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally

evaluated bone marrow aspirate/biopsy assessments (derived response). Participants were in CRh when they could not be classified as being in CR and had bone marrow blasts < 5% and partial hematologic recovery ANC $\geq 0.5 \times 10^9/L$ and platelets $\geq 50 \times 10^9/L$. There should not be evidence of extramedullary leukemia. The analysis population was the FAS. CRh was calculated only for participants who were FLT3 mutation positive. Data could not be calculated due to low number of events, and is denoted as "99999."

End point type	Secondary
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End point timeframe:

Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	8	12	56
Units: percentage of participants				
number (confidence interval 95%)	7.1 (0.2 to 33.9)	0 (-99999 to 99999)	8.3 (0.2 to 38.5)	10.7 (4.0 to 21.9)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	89	10	2	
Units: percentage of participants				
number (confidence interval 95%)	7.9 (3.2 to 15.5)	20.0 (2.5 to 55.6)	0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Composite CR (CRc)

End point title	Percentage of Participants with Composite CR (CRc)
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End point description:

CRc was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally evaluated bone marrow aspirate/biopsy assessments (derived response). Participants were in CRc when they had achieved either CR, complete remission with incomplete platelet recovery (CRp, defined as had achieved CR except for incomplete platelet recovery ($< 100 \times 10^9/L$) or complete remission with incomplete hematologic recovery (CRi, defined as had fulfilled all the criteria for CR except for incomplete hematological recovery with residual neutropenia $< 1 \times 10^9/L$ with or without complete platelet recovery; RBC platelet transfusion independence not required). The analysis population was the FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	7.1 (0.2 to 33.9)	0 (-99999 to 99999)	41.7 (15.2 to 72.3)	46.4 (33.0 to 60.3)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	50.0 (1.3 to 98.7)	0 (-99999 to 99999)	16.7 (2.1 to 48.4)	7.1 (0.2 to 33.9)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	12.5 (1.6 to 38.3)	0 (-99999 to 99999)	29.2 (12.6 to 51.1)	38.6 (27.2 to 51.0)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	40.4 (30.2 to 51.4)	30.0 (6.7 to 65.2)	0 (-99999 to 99999)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	9.1 (0.2 to 41.3)	0 (-99999 to 99999)	0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	37.0 (27.6 to 47.2)	15.0 (3.2 to 37.9)	0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Partial Remission (PR)

End point title	Percentage of Participants with Partial Remission (PR)
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End point description:

PR was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally evaluated bone marrow aspirate/biopsy assessments (derived response). Participants were classified as being in PR when they had bone marrow regenerating normal hematopoietic cells with evidence of peripheral recovery with no (or only a few regenerating) circulating blasts and with a decrease of at least 50% in the percentage of blasts in the bone marrow aspirate with the total marrow blasts between 5% and 25%. A value of less or equal than 5% blasts was also considered a PR if Auer rods were present. There should be no evidence of extramedullary leukemia. The analysis population was the FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	7.1 (0.2 to 33.9)	37.5 (8.5 to 75.5)	25.0 (5.5 to 57.2)	7.1 (2.0 to 17.3)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)	7.1 (0.2 to 33.9)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	6.3 (0.2 to 30.2)	18.8 (4.0 to 45.6)	12.5 (2.7 to 32.4)	7.1 (2.4 to 15.9)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	7.9 (3.2 to 15.5)	30.0 (6.7 to 65.2)	50.0 (1.3 to 98.7)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	9.1 (0.2 to 41.3)	0 (-99999 to 99999)	0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	8.0 (3.5 to 15.2)	15.0 (3.2 to 37.9)	33.3 (0.8 to 90.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Best Response

End point title	Percentage of Participants with Best Response
End point description:	
Best response was defined according to modified Cheson criteria (2003), using centrally evaluated myeloblast counts from bone marrow aspirate/biopsy assessments and centrally evaluated hematology results; if neither central bone marrow aspirate nor biopsy was available, myeloblast was imputed with locally evaluated bone marrow aspirate/biopsy assessments (derived response). BR was defined as the best measured response for all visits (in the order of CR, CRp, CRi, and PR) post-treatment. Participants who achieved the best response of CR, CRp, CRi or PR were classified as responders. Participants who did not achieve at least PR were considered as non-responders. The analysis population was the FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."	
End point type	Secondary
End point timeframe:	
Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	14.3 (1.8 to 42.8)	37.5 (8.5 to 75.5)	66.7 (34.9 to 90.1)	53.6 (39.7 to 67.0)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	50.0 (1.3 to 98.7)	0 (-99999 to 99999)	16.7 (2.1 to 48.4)	14.3 (1.8 to 42.8)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	18.8 (4.0 to 45.6)	18.8 (4.0 to 45.6)	41.7 (22.1 to 63.4)	45.7 (33.7 to 58.1)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89, 10, 2]	48.3 (37.6 to 59.2)	60.0 (26.2 to 87.8)	50.0 (1.3 to 98.7)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	18.2 (2.3 to 51.8)	0 (-99999 to 99999)	0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	45.0 (35.0 to 55.3)	30.0 (11.9 to 54.3)	33.3 (0.8 to 90.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Remission and Complete Remission with Partial Hematologic Recovery (CR/CRh)

End point title	Percentage of Participants with Complete Remission and Complete Remission with Partial Hematologic Recovery (CR/CRh)
End point description:	
<p>Participants with CR/CRh were defined as participants who achieved either CR or CRh. Participants with CR had bone marrow regenerating normal hematopoietic cells, achieved a morphologic leukemia-free state, had an ANC $> 1 \times 10^9/L$, platelet count $\geq 100 \times 10^9/L$, and normal marrow differential with $< 5\%$ blasts, had been RBC and platelet transfusion independent (defined as 1 week without RBC transfusion and 1 week without platelet transfusion). Also, there had been no presence of Auer rods, no evidence of extramedullary leukemia, and blast counts in peripheral blood had been $\leq 2\%$. Participants with CRh could not be in CR and had bone marrow blasts $< 5\%$, partial hematologic recovery ANC $\geq 0.5 \times 10^9/L$ and platelets $\geq 50 \times 10^9/L$ and should not have evidence of extramedullary leukemia. The analysis population was the FAS. CR/CRh was calculated only for participants who were FLT3 mutation positive. Data could not be calculated due to low number of events, and is denoted as "+/- 99999."</p>	
End point type	Secondary

End point timeframe:

Up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	8	12	56
Units: percentage of participants				
number (confidence interval 95%)	7.1 (0.2 to 33.9)	0 (-99999 to 99999)	25.0 (5.5 to 57.2)	23.2 (13.0 to 36.4)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	89	10	2	
Units: percentage of participants				
number (confidence interval 95%)	19.1 (11.5 to 28.8)	30.0 (6.7 to 65.2)	0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CR (DCR)

End point title	Duration of CR (DCR)
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End point description:

DCR was defined as the time from the date of first CR until the date of documented relapse for participants who achieved CR. Participants who died without report of relapse were considered non-events and censored at their last relapse-free disease assessment date. Other participants who did not relapse on study were considered non-events and censored at the last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CR were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999." DCR was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From date of remission until end of study (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[16]	2	7
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=0, 0, 2, 7, 10, 1, 0]	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)	99999 (86.0 to 99999)
FLT3 Mutation Negative [N=1, 0, 0, 0, 0, 0, 0]	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)
All Participants [N=1, 0, 2, 7, 10, 1, 0]	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)	99999 (86.0 to 99999)

Notes:

[16] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	1	0 ^[17]	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=0, 0, 2, 7, 10, 1, 0]	419.0 (64.0 to 99999)	99999 (99999 to 99999)	(to)	
FLT3 Mutation Negative [N=1, 0, 0, 0, 0, 0, 0]	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
All Participants [N=1, 0, 2, 7, 10, 1, 0]	419.0 (64.0 to 99999)	99999 (99999 to 99999)	(to)	

Notes:

[17] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CRp (DCRp)

End point title	Duration of CRp (DCRp)
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End point description:

DCRp was defined as the time from the date of first CRp until the date of documented relapse for participants who achieved CRp. Participants who died without report of relapse were considered non-events and censored at their last relapse-free disease assessment date. Other participants who did not relapse on study were considered non-events and censored at the last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CRp were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999." DCRp was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From date of remission until end of study (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[18]	0 ^[19]	1	6
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=0, 0, 1, 6, 12, 2, 0]	(to)	(to)	99999 (99999 to 99999)	99999 (57.0 to 99999)
FLT3 Mutation Negative [N=0, 0, 0, 0, 0, 0, 0]	(to)	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)
All Participants [N=0, 0, 1, 6, 12, 2, 0]	(to)	(to)	99999 (99999 to 99999)	99999 (57.0 to 99999)

Notes:

[18] - Data could not be calculated due to low number of events.

[19] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	12	2	0 ^[20]	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=0, 0, 1, 6, 12, 2, 0]	450.0 (43.0 to 99999)	99999 (99999 to 99999)	(to)	
FLT3 Mutation Negative [N=0, 0, 0, 0, 0, 0, 0]	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
All Participants [N=0, 0, 1, 6, 12, 2, 0]	450.0 (43.0 to 99999)	99999 (99999 to 99999)	(to)	

Notes:

[20] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CRi (DCRi)

End point title	Duration of CRi (DCRi)
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End point description:

DCRi was defined as the time from the date of first CRi until the date of documented relapse for participants who achieved CRi. Participants who died without report of relapse and participants who did not relapse were considered non-events and censored at the last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CRi were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999." DCRi was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From date of remission until end of study (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[21]	7	24
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=1, 0, 5, 23, 30, 1, 0]	99999 (99999 to 99999)	(to)	99999 (79.0 to 99999)	120.0 (56.0 to 383.0)
FLT3 Mutation Negative [N=0, 0, 2, 1, 0, 0, 0]	99999 (99999 to 99999)	(to)	41.0 (22.0 to 60.0)	99.0 (-99999 to 99999)
All Participants [N=1, 0, 7, 24, 31, 1, 0]	99999 (99999 to 99999)	(to)	79.0 (22.0 to 99999)	120.0 (58.0 to 383.0)

Notes:

[21] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	1	0 ^[22]	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=1, 0, 5, 23, 30, 1, 0]	191.0 (57.0 to 420.0)	99999 (99999 to 99999)	(to)	
FLT3 Mutation Negative [N=0, 0, 2, 1, 0, 0, 0]	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
All Participants [N=1, 0, 7, 24, 31, 1, 0]	191.0 (57.0 to 420.0)	99999 (99999 to 99999)	(to)	

Notes:

[22] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CRh (DCRh)

End point title	Duration of CRh (DCRh)
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End point description:

DCRh was defined as the time from the date of first CRh until the date of documented relapse for participants who achieved CRh but did not have a best response of CR. Participants who died without report of relapse and participants who did not relapse were considered non-events and censored at the last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CRh were included in the analysis. DCRh was calculated only for participants who were FLT3 mutation positive. Data could not be calculated due to low number of events, and is denoted as "+/- 99999." DCRh was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From date of remission until end of study (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[23]	1	6
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)	64.0 (18.0 to 85.0)

Notes:

[23] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	2	0 ^[24]	
Units: days				
median (confidence interval 95%)	101.0 (29.0 to 99999)	99999 (99999 to 99999)	(to)	

Notes:

[24] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CRc (DCRc)

End point title	Duration of CRc (DCRc)
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End point description:

DCRc was defined as the time from the date of first CRc until the date of documented relapse for participants who achieved CRc. Participants who died without report of relapse and participants who did not relapse were considered non-events and censored at the last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CRc were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999." DCRc was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From date of remission until end of study (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	0 ^[25]	7	27
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=1, 0, 5, 26, 36, 3, 0]	99999 (99999 to 99999)	(to)	99999 (79.0 to 99999)	98.0 (57.0 to 307.0)
FLT3 Mutation Negative [N=1, 0, 2, 1, 1, 0, 0]	99999 (99999 to 99999)	(to)	41.0 (22.0 to 60.0)	99.0 (-99999 to 99999)
All Participants [N=2, 0, 7, 27, 37, 3, 0]	99999 (99999 to 99999)	(to)	79.0 (22.0 to 99999)	98.0 (58.0 to 307.0)

Notes:

[25] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	37	3	0 ^[26]	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=1, 0, 5, 26, 36, 3, 0]	191.0 (101.0 to 465.0)	99999 (99999 to 99999)	(to)	
FLT3 Mutation Negative [N=1, 0, 2, 1, 1, 0, 0]	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
All Participants [N=2, 0, 7, 27, 37, 3, 0]	191.0 (101.0 to 465.0)	99999 (99999 to 99999)	(to)	

Notes:

[26] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CR/CRh (DCRCRr)

End point title	Duration of CR/CRh (DCRCRr)
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End point description:

DCRCRr was defined as the time from the date of first DCRCRr until the date of documented relapse for participants who achieved CR or CRh. For participants who achieved both CR and CRh, the first CR date or CRh date, whichever occurred first, was used. Participants who died without report of relapse and participants who did not relapse were considered non-events and censored at the last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CR or CRh were included in the analysis. DCRCRr was calculated only for participants who were FLT3 mutation positive. Data could not be calculated due to low number of events, and is denoted as "+/99999." DCRCRr was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From date of remission until end of study (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[27]	3	13
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)	307.0 (56.0 to 99999)

Notes:

[27] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	17	3	0 ^[28]	

Units: days				
median (confidence interval 95%)	308.0 (101.0 to 99999)	99999 (99999 to 99999)	(to)	

Notes:

[28] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response
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End point description:

Duration of response was defined as the time from the date of either first CRc or PR until the date of documented relapse of any type for participants who achieved CRc or PR. Participants who died without report of relapse and participants who did not relapse were considered non-events and censored at the last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CRc or PR were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999." Duration of response was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From date of remission until end of study (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	10	32
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=2, 3, 8, 30, 43, 6, 1]	99999 (99999 to 99999)	99999 (99999 to 99999)	88.0 (9.0 to 99999)	141.0 (58.0 to 383.0)
FLT3 Mutation Negative [N=1, 0, 2, 2, 2, 0, 0]	99999 (99999 to 99999)	99999 (99999 to 99999)	41.0 (22.0 to 60.0)	109.5 (99.0 to 120.0)
All Participants [N=3, 3, 10, 32, 45, 6, 1]	99999 (99999 to 99999)	99999 (99999 to 99999)	79.0 (9.0 to 99999)	126.0 (58.0 to 307.0)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	45	6	1	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=2, 3, 8, 30, 43, 6, 1]	220.0 (111.0 to 482.0)	59.0 (15.0 to 59.0)	99999 (99999 to 99999)	
FLT3 Mutation Negative [N=1, 0, 2, 2, 2, 0, 0]	85.0 (-99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	
All Participants [N=3, 3, 10, 32, 45, 6, 1]	220.0 (85.0 to 482.0)	59.0 (15.0 to 59.0)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to CR (TTCR)

End point title	Time to CR (TTCR)
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End point description:

TTCR was defined as the time from the first dose of study drug until the date of first CR. The analysis population was the FAS. Only participants who achieved CR were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[29]	2	7
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=0, 0, 2, 7, 10, 1, 0]	99999 (99999 to 99999)	(to)	171.5 (28 to 315)	141.0 (29 to 364)
FLT3 Mutation Negative [N=1, 0, 0, 0, 0, 0, 0]	30.0 (30 to 30)	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)
All Participants [N=1, 0, 2, 7, 10, 1, 0]	30.0 (30 to 30)	(to)	171.5 (28 to 315)	141.0 (29 to 364)

Notes:

[29] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	1	0 ^[30]	
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=0, 0, 2, 7, 10, 1, 0]	93.0 (27 to 225)	56.0 (56 to 56)	(to)	
FLT3 Mutation Negative [N=1, 0, 0, 0, 0, 0, 0]	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
All Participants [N=1, 0, 2, 7, 10, 1, 0]	93.0 (27 to 225)	56.0 (56 to 56)	(to)	

Notes:

[30] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to CRp (TTCRp)

End point title	Time to CRp (TTCRp)
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End point description:

TTCRp was defined as the time from the first dose of study drug until the date of first CRp. TTCRp was evaluated for participants who achieved CRp. The analysis population was the FAS. Only participants who achieved CRp were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[31]	0 ^[32]	1	6
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=0, 0, 1, 6, 12, 2, 0]	(to)	(to)	140.0 (140 to 140)	195.0 (30 to 418)
FLT3 Mutation Negative [N=0, 0, 0, 0, 0, 0, 0]	(to)	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)
All Participants [N=0, 0, 1, 6, 12, 2, 0]	(to)	(to)	140.0 (140 to 140)	195.0 (30 to 418)

Notes:

[31] - Data could not be calculated due to low number of events.

[32] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	12	2	0 ^[33]	
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=0, 0, 1, 6, 12, 2, 0]	84.5 (28 to 392)	29.0 (28 to 30)	(to)	
FLT3 Mutation Negative [N=0, 0, 0, 0, 0, 0, 0]	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
All Participants [N=0, 0, 1, 6, 12, 2, 0]	84.5 (28 to 392)	29.0 (28 to 30)	(to)	

Notes:

[33] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to CRi (TTCRi)

End point title	Time to CRi (TTCRi)
End point description:	
TTCRi was defined as the time from the first dose of study drug until the date of first CRi. TTCRi was evaluated for participants who achieved CRi. The analysis population was the FAS. Only participants who achieved CRi were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999."	
End point type	Secondary
End point timeframe:	
From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[34]	7	24
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=1, 0, 5, 23, 30, 1, 0]	57.0 (57 to 57)	(to)	57.0 (31 to 70)	57.0 (26 to 170)
FLT3 Mutation Negative [N=0, 0, 2, 1, 1, 0, 0]	99999 (99999 to 99999)	(to)	71.5 (71 to 72)	30.0 (30 to 30)
All Participants [N=1, 0, 7, 24, 31, 1, 0]	57.0 (57 to 57)	(to)	64.0 (31 to 72)	43.5 (26 to 170)

Notes:

[34] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	1	0 ^[35]	
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=1, 0, 5, 23, 30, 1, 0]	39.5 (26 to 133)	28.0 (28 to 28)	(to)	
FLT3 Mutation Negative [N=0, 0, 2, 1, 1, 0, 0]	30.0 (30 to 30)	99999 (99999 to 99999)	(to)	
All Participants [N=1, 0, 7, 24, 31, 1, 0]	35.0 (26 to 133)	28.0 (28 to 28)	(to)	

Notes:

[35] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First CR/CRh (TTFCCRh)

End point title	Time to First CR/CRh (TTFCCRh)
End point description:	
TTFCCRh was defined as the time from the first dose of study drug until the date of first either CR or CRh. TTFCCRh was evaluated for participants who achieved CR or CRh. For participants who achieve both CR and CRh, the first CR date or CRh date, whichever occurs first was used. The analysis population was the FAS. Only participants who achieved CR or CRh were included in the analysis. TTFCCRh was calculated only for participants who were FLT3 mutation positive.	

End point type	Secondary
End point timeframe:	
From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[36]	3	13
Units: days				
median (full range (min-max))	57.0 (57 to 57)	(to)	57.0 (28 to 140)	59.0 (29 to 280)

Notes:

[36] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	17	3	0 ^[37]	
Units: days				
median (full range (min-max))	57.0 (27 to 245)	28.0 (28 to 30)	(to)	

Notes:

[37] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Best CR/CRh (TTBCRCR_h)

End point title	Time to Best CR/CR _h (TTBCRCR _h)
End point description:	
TTBCRCR _h was defined as the time from the first dose of study drug until the first date that the best response of CR or CR _h was achieved. TTBCRCR _h was evaluated for participants who achieved CR or CR _h . For participants who achieve both CR and CR _h , the first CR date was used. The analysis population was the FAS. Only participants who achieved CR or CR _h were included in the analysis. TTBCRCR _h was calculated only for participants who were FLT3 mutation positive.	
End point type	Secondary
End point timeframe:	
From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	0 ^[38]	3	13
Units: days				
median (full range (min-max))	57.0 (57 to 57)	(to)	57.0 (28 to 315)	63.0 (29 to 364)

Notes:

[38] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	17	3	0 ^[39]	
Units: days				
median (full range (min-max))	88.0 (27 to 245)	30.0 (28 to 56)	(to)	

Notes:

[39] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to CRc (TTCRc)

End point title	Time to CRc (TTCRc)
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End point description:

TTCRc was defined as the time from the first dose of study drug until the date of first CRc. TTCRc was evaluated for participants who achieved CRc. The analysis population was the FAS. Only participants who achieved CRc were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	0 ^[40]	7	27
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=1, 0, 5, 26, 36, 3, 0]	57.0 (57 to 57)	(to)	56.0 (28 to 64)	30.0 (26 to 211)
FLT3 Mutation Negative [N=1, 0, 2, 1, 1, 0, 0]	30.0 (30 to 30)	(to)	71.5 (71 to 72)	30.0 (30 to 30)
All Participants [N=2, 0, 7, 27, 37, 3, 0]	43.5 (30 to 57)	(to)	57.0 (28 to 72)	30.0 (26 to 211)

Notes:

[40] - Data could not be calculated due to low number of events

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	37	3	0 ^[41]	
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=1, 0, 5, 26, 36, 3, 0]	31.5 (26 to 197)	28.0 (28 to 30)	(to)	
FLT3 Mutation Negative [N=1, 0, 2, 1, 1, 0, 0]	30.0 (30 to 30)	99999 (99999 to 99999)	(to)	
All Participants [N=2, 0, 7, 27, 37, 3, 0]	31.0 (26 to 197)	28.0 (28 to 30)	(to)	

Notes:

[41] - Data could not be calculated due to low number of events

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response (TTR)

End point title	Time to Response (TTR)
End point description:	
TTR was defined as the time from the first dose of study drug until the date of either first CRc or PR. TTR was evaluated for participants who achieved CRc or PR. The analysis population was the FAS. Only participants who achieved CRc or PR were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999."	
End point type	Secondary
End point timeframe:	
From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	10	32
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=2, 3, 8, 30, 43, 6, 1]	61.5 (29 to 94)	57.0 (31 to 64)	31.0 (28 to 59)	29.0 (26 to 211)
FLT3 Mutation Negative [N=1, 0, 2, 2, 2, 0, 0]	30.0 (30 to 30)	99999 (99999 to 99999)	71.5 (71 to 72)	29.5 (29 to 30)
All Participants [N=3, 3, 10, 32, 45, 6, 1]	30.0 (29 to 94)	57.0 (31 to 64)	43.5 (28 to 72)	29.0 (26 to 211)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	45	6	1	
Units: days				
median (full range (min-max))				

FLT3 Mutation Positive [N=2, 3, 8, 30, 43, 6, 1]	29.0 (26 to 197)	28.0 (26 to 61)	31.0 (31 to 31)	
FLT3 Mutation Negative [N=1, 0, 2, 2, 2, 0, 0]	29.5 (29 to 30)	99999 (99999 to 99999)	99999 (99999 to 99999)	
All Participants [N=3, 3, 10, 32, 45, 6, 1]	29.0 (26 to 197)	28.0 (26 to 61)	31.0 (31 to 31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Best Response (TTBR)

End point title	Time to Best Response (TTBR)
End point description:	
TTBR was defined as the time from the first dose of study drug until the first disease assessment date when participant achieved best response. TTBR was evaluated in participants who achieved best response of CR, CRp, CRi, or PR. The analysis population was the FAS. Only participants who achieved CR, CRp, CRi, or PR were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999."	
End point type	Secondary
End point timeframe:	
From first dose of study drug up to end of treatment (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)	

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	10	32
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=2, 3, 8, 30, 43, 6, 1]	75.5 (57 to 94)	57.0 (31 to 64)	44.0 (28 to 315)	43.5 (26 to 364)
FLT3 Mutation Negative [N=1, 0, 2, 2, 2, 0, 0]	30.0 (30 to 30)	99999 (99999 to 99999)	71.5 (71 to 72)	29.5 (29 to 30)
All Participants [N=3, 3, 10, 32, 45, 6, 1]	57.0 (30 to 94)	57.0 (31 to 64)	58.0 (28 to 315)	30.0 (26 to 364)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	45	6	1	
Units: days				
median (full range (min-max))				
FLT3 Mutation Positive [N=2, 3, 8, 30, 43, 6, 1]	57.0 (26 to 245)	29.0 (26 to 61)	31.0 (31 to 31)	
FLT3 Mutation Negative [N=1, 0, 2, 2, 2, 0, 0]	29.5 (29 to 30)	99999 (99999 to 99999)	99999 (99999 to 99999)	
All Participants [N=3, 3, 10, 32, 45, 6, 1]	56.0 (26 to 245)	29.0 (26 to 61)	31.0 (31 to 31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
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End point description:

OS was defined as the time from the date of first dose of study drug until the date of death from any cause. For a participant who was not known to have died by the end of study follow-up, OS was censored at the date of last contact. The analysis population was the FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999." OS was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to end of study (median time on study was 157.0 days, minimum of 5 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89,10, 2]	123.0 (17.0 to 267.0)	199.5 (56.0 to 905.0)	197.5 (61.0 to 329.0)	246.0 (190.0 to 309.0)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	99999 (227.0 to 99999)	71.5 (5.0 to 180.0)	136.0 (14.0 to 314.0)	144.0 (83.0 to 195.0)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	149.5 (31.0 to 267.0)	95.0 (55.0 to 195.0)	154.0 (74.0 to 299.0)	216.0 (161.0 to 285.0)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89,10, 2]	214.0 (126.0 to 264.0)	157.0 (20.0 to 218.0)	204.0 (51.0 to 357.0)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	67.0 (21.0 to 336.0)	68.0 (8.0 to 249.0)	89.0 (-99999 to 99999)	
All Participants [N=16, 16, 24, 70, 100, 20, 3]	176.0 (124.0 to 253.0)	128.5 (36.0 to 199.0)	89.0 (51.0 to 357.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Event Free Survival (EFS)

End point title	Event Free Survival (EFS)
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End point description:

EFS was defined as the time from the date of first dose of study drug until the date of documented relapse, treatment failure or death from any cause, whichever occurred first. For a participant with none of these events, EFS was censored at the date of last relapse-free disease assessment. A participant without post-treatment disease assessment was censored at randomization date. Treatment failure included those participants who discontinued the treatment due to "progressive disease" or "lack of efficacy" without a previous response of CR, CRp, CRi or PR. Treatment failure date referred to the start of new anti-leukemia therapy or the last treatment evaluation date when new anti-leukemia therapy date was not available. For participants who were censored, last relapse-free disease assessment date referred to the participant's last disease assessment date. The analysis population was the FAS. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

From first dose of study drug up to end of study (median time on study was 157.0 days, minimum of 5 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	16	24	70
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89,10, 2]	52.0 (14.0 to 88.0)	109.0 (29.0 to 357.0)	93.5 (61.0 to 127.0)	112.0 (92.0 to 143.0)
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	58.0 (-99999 to 99999)	39.0 (5.0 to 67.0)	74.0 (12.0 to 131.0)	85.5 (37.0 to 126.0)
All Participants [N=16, 16, 24, 70, 100, 20, 3]	58.0 (19.0 to 88.0)	55.5 (38.0 to 92.0)	76.0 (61.0 to 119.0)	108.0 (90.0 to 126.0)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	20	3	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=14, 8, 12, 56, 89,10, 2]	121.0 (92.0 to 155.0)	85.0 (11.0 to 157.0)	86.0 (51.0 to 121.0)	
FLT3 Mutation Negative [N=2, 8, 12, 14, 11, 10, 1]	45.0 (21.0 to 113.0)	43.0 (8.0 to 83.0)	71.0 (-99999 to 99999)	

All Participants [N=16, 16, 24, 70, 100, 20, 3]	118.0 (88.0 to 140.0)	65.0 (20.0 to 100.0)	71.0 (51.0 to 121.0)	
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Statistical analyses

No statistical analyses for this end point

Secondary: Leukemia Free Survival (LFS)

End point title	Leukemia Free Survival (LFS)
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End point description:

LFS was defined as the time from the date of first CRc until the date of documented relapse or death for participants who achieved CRc. For a participant who was not known to have relapsed or died, LFS was censored on the date of last relapse-free disease assessment date. The analysis population was the FAS. Only participants who achieved CRc were included in the analysis. Data could not be calculated due to low number of events, and is denoted as "+/-99999." LFS was calculated using Kaplan-Meier method and therefore data are estimated.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to end of study (median time on study was 157.0 days, minimum of 5 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	0 ^[42]	7	27
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=1, 0, 5, 26, 36, 3, 0]	242.0 (-99999 to 99999)	(to)	98.0 (56.0 to 1126.0)	98.0 (58.0 to 187.0)
FLT3 Mutation Negative [N=1, 0, 2, 1, 1, 0, 0]	99999 (99999 to 99999)	(to)	41.0 (22.0 to 60.0)	99.0 (-99999 to 99999)
All Participants [N=2, 0, 7, 27, 37, 3, 0]	242.0 (-99999 to 99999)	(to)	79.0 (22.0 to 1126.0)	98.0 (58.0 to 187.0)

Notes:

[42] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	37	3	0 ^[43]	
Units: days				
median (confidence interval 95%)				
FLT3 Mutation Positive [N=1, 0, 5, 26, 36, 3, 0]	146.0 (47.0 to 247.0)	296.0 (130.0 to 462.0)	(to)	
FLT3 Mutation Negative [N=1, 0, 2, 1, 1, 0, 0]	38.0 (-99999 to 99999)	99999 (99999 to 99999)	(to)	
All Participants [N=2, 0, 7, 27, 37, 3, 0]	146.0 (45.0 to 247.0)	296.0 (130.0 to 462.0)	(to)	

Notes:

[43] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Transfusion Conversion

End point title	Percentage of Participants Who Achieved Transfusion Conversion
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End point description:

Participants who achieved transfusion conversion were defined as participants who were transfusion dependent at baseline period but became transfusion independent at postbaseline period against participants who were transfusion dependent at baseline period. Participants were considered baseline transfusion dependent if there were RBC or platelet transfusions within the baseline period. Participants were considered postbaseline transfusion independent if they were on treatment ≥ 84 days, and if there was one consecutive 56 days without any RBC or platelet transfusion within postbaseline period. If participants were on treatment >28 days but <84 days, and there was no RBC or platelet transfusion within postbaseline period, or on treatment ≤ 28 days, postbaseline transfusion status was not evaluable. FAS, with participants who were transfusion dependent at baseline & had evaluable postbaseline transfusion status. Data could not be calculated due to low number of events "+/-99999."

End point type	Secondary
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End point timeframe:

Baseline (28 days prior to first dose until 28 days after the first dose) and postbaseline (from 29 days after first dose date until last dose date); median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	8	16	49
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=6, 5, 8, 40, 57, 4, 1]	0 (-99999 to 99999)	0 (-99999 to 99999)	37.5 (8.5 to 75.5)	27.5 (14.6 to 43.9)
FLT3 Mutation Negative [N=1, 3, 8, 9, 6, 4, 1]	99999 (99999 to 99999)	99999 (99999 to 99999)	12.5 (0.3 to 52.7)	22.2 (2.8 to 60.0)
All Participants [N=7, 8, 16, 49, 63, 8, 2]	99999 (99999 to 99999)	99999 (99999 to 99999)	25.0 (7.3 to 52.4)	26.5 (14.9 to 41.1)

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	63	8	2	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=6, 5, 8, 40, 57, 4, 1]	40.4 (27.6 to 54.2)	99999 (99999 to 99999)	99999 (99999 to 99999)	

FLT3 Mutation Negative [N=1, 3, 8, 9, 6, 4, 1]	33.3 (4.3 to 77.7)	99999 (99999 to 99999)	99999 (99999 to 99999)	
All Participants [N=7, 8, 16, 49, 63, 8, 2]	39.7 (27.6 to 52.8)	99999 (99999 to 99999)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Transfusion Maintenance

End point title	Percentage of Participants Who Achieved Transfusion Maintenance
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End point description:

Participants who achieved transfusion maintenance were defined as participants who were transfusion independent at baseline period and still maintained transfusion independent at postbaseline period against participants who were transfusion independent at baseline period. FAS, with participants who was transfusion independent at baseline and had evaluable postbaseline transfusion status. Data could not be calculated due to low number of events, and is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Baseline (28 days prior to first dose until 28 days after the first dose) and postbaseline (from 29 days after first dose date until last dose date); (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

End point values	Gilteritinib 20 mg	Gilteritinib 40 mg	Gilteritinib 80 mg	Gilteritinib 120 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[44]	0 ^[45]	1	7
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=0, 0, 1, 4, 10, 0, 1]	(to)	(to)	100.0 (2.5 to 100.0)	75.0 (19.4 to 99.4)
FLT3 Mutation Negative [N=0, 0, 0, 3, 0, 0, 0]	(to)	(to)	99999 (99999 to 99999)	33.3 (0.8 to 90.6)
All Participants [N=0, 0, 1, 7, 10, 0, 1]	(to)	(to)	100.0 (2.5 to 100.0)	57.1 (18.4 to 90.1)

Notes:

[44] - Data could not be calculated due to low number of events.

[45] - Data could not be calculated due to low number of events.

End point values	Gilteritinib 200 mg	Gilteritinib 300 mg	Gilteritinib 450 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	0 ^[46]	1	
Units: percentage of participants				
number (confidence interval 95%)				
FLT3 Mutation Positive [N=0, 0, 1, 4, 10, 0, 1]	80.0 (44.4 to 97.5)	(to)	100.0 (2.5 to 100)	
FLT3 Mutation Negative [N=0, 0, 0, 3, 0, 0, 0]	99999 (99999 to 99999)	(to)	99999 (99999 to 99999)	
All Participants [N=0, 0, 1, 7, 10, 0, 1]	80.0 (44.4 to 97.5)	(to)	100.0 (2.5 to 100.0)	

Notes:

[46] - Data could not be calculated due to low number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC24 of Gilteritinib in Co-administration with Voriconazole

End point title	AUC24 of Gilteritinib in Co-administration with Voriconazole ^[47]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 20 mg gilertitinib and voriconazole. Data that could not be calculated due to a sample size of 1 is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Cycle 1 day 15 and cycle 2 day 1: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (gilteritinib)

Notes:

[47] - 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: Only participants administered with 20 mg gilertitinib and voriconazole are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Cycle 2 day 1	919.3 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Gilteritinib in Co-administration with Voriconazole

End point title	Cmax of Gilteritinib in Co-administration with Voriconazole ^[48]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 20 mg gilertitinib and voriconazole. Data that could not be calculated due to a sample size of 1 is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Cycle 1 day 15 and cycle 2 day 1: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (gilteritinib)

Notes:

[48] - 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: Only participants administered with 20 mg gilteritinib and voriconazole are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: ng/mL				
arithmetic mean (standard deviation)				
Cycle 2 day 1	63.79 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of Gilteritinib in Co-administration with Voriconazole

End point title	AUClast of Gilteritinib in Co-administration with Voriconazole ^[49]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 20 mg gilteritinib and voriconazole. Data that could not be calculated due to a sample size of 1 is denoted as "+/-99999."

End point type	Secondary
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End point timeframe:

Cycle 1 day 15 and cycle 2 day 1: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (gilteritinib)

Notes:

[49] - 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: Only participants administered with 20 mg gilteritinib and voriconazole are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Cycle 2 day 1	919.3 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of Gilteritinib in Co-administration with Voriconazole

End point title	Tmax of Gilteritinib in Co-administration with Voriconazole ^[50]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 20 mg gilteritinib and voriconazole.

End point type	Secondary
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End point timeframe:

Cycle 1 day 15 and cycle 2 day 1: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (gilteritinib)

Notes:

[50] - 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: Only participants administered with 20 mg gilteritinib and voriconazole are applicable to this endpoint.

End point values	Gilteritinib 20 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: hours				
median (full range (min-max))				
Cycle 2 day 1	2.08 (2.08 to 2.08)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUC24 of Midazolam Administered With and Without Gilteritinib

End point title	AUC24 of Midazolam Administered With and Without
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)

Notes:

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

Justification: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Midazolam Alone (Day -1) [N=15]	66.55 (± 57.70)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=8]	81.56 (± 65.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUC24 of Metabolite 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib

End point title	AUC24 of Metabolite 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib ^[52]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)

Notes:

[52] - 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: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Midazolam Alone (Day -1) [N=15]	20.44 (± 24.80)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=8]	23.10 (± 21.64)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Midazolam Administered With and Without Gilteritinib

End point title	Cmax of Midazolam Administered With and Without
End point description: Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.	
End point type	Secondary
End point timeframe: Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)	

Notes:

[53] - 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: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: ng/mL				
arithmetic mean (standard deviation)				
Midazolam Alone (Day -1) [N=16]	14.68 (± 8.923)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=9]	18.45 (± 9.452)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib

End point title	Cmax of 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib ^[54]
End point description: Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.	
End point type	Secondary
End point timeframe: Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)	

Notes:

[54] - 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: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: ng/mL				
arithmetic mean (standard deviation)				
Midazolam Alone (Day -1) [N=16]	4.562 (± 2.858)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=9]	5.053 (± 3.158)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of Midazolam Administered With and Without Gilteritinib

End point title	AUClast of Midazolam Administered With and Without Gilteritinib ^[55]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)

Notes:

[55] - 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: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Midazolam Alone (Day -1) [N=16]	59.48 (± 59.49)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=9]	82.44 (± 64.25)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib

End point title	AUClast of 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib ^[56]
End point description: Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.	
End point type	Secondary
End point timeframe: Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)	
Notes: [56] - 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: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.	

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Midazolam Alone (Day -1) [N=16]	17.05 (± 24.70)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=9]	23.58 (± 22.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of Midazolam Administered With and Without Gilteritinib

End point title	Tmax of Midazolam Administered With and Without
End point description: Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.	
End point type	Secondary
End point timeframe: Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)	
Notes: [57] - 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: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.	

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: hours				

median (full range (min-max))				
Midazolam Alone (Day -1) [N=16]	0.5000 (0.367 to 2.00)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=9]	1.00 (0.317 to 4.13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib

End point title	Tmax of 1-Hydroxymidazolam After Administration of Midazolam With and Without Gilteritinib ^[58]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 300 mg gilteritinib and midazolam.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 2, 4, 6, 24 hours postdose (midazolam)

Notes:

[58] - 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: Only participants administered with 300 mg gilteritinib and midazolam are applicable to this endpoint.

End point values	Gilteritinib 300 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: hours				
median (full range (min-max))				
Midazolam Alone (Day -1) [N=16]	0.5583 (0.483 to 2.00)			
Midazolam + Gilteritinib (Cycle 1 Day 15) [N=9]	1.00 (0.317 to 4.13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-time Curve From the Time of Dosing Extrapolated to Time Infinity (AUCinf) of Cephalexin Administered With and Without Gilteritinib

End point title	Area Under the Concentration-time Curve From the Time of Dosing Extrapolated to Time Infinity (AUCinf) of Cephalexin Administered With and Without Gilteritinib ^[59]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS,

with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
End point timeframe:	
Day -1 and cycle 1 day 15: predose, 0.5, 1, 1.5, 2, 3, 4, 6, 24 hours postdose (cephalexin)	

Notes:

[59] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=18]	57650 (\pm 20386)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=13]	51873 (\pm 18819)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Cephalexin Administered With and Without Gilteritinib

End point title	Cmax of Cephalexin Administered With and Without
End point description:	
Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.	
End point type	Secondary
End point timeframe:	
Day -1 and cycle 1 day 15: predose, 0.5, 1, 1.5, 2, 3, 4, 6, 24 hours postdose (cephalexin)	

Notes:

[60] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: ng/mL				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=20]	17688 (\pm 6680)			

Cephalexin + Gilteritinib (Cycle 1 day 15) [N=16]	16075 (\pm 4606)			
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Statistical analyses

No statistical analyses for this end point

Secondary: AUClast of Cephalexin Administered With and Without Gilteritinib

End point title	AUClast of Cephalexin Administered With and Without Gilteritinib ^[61]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 1.5, 2, 3, 4, 6, 24 hours postdose (cephalexin)

Notes:

[61] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: ng*h/mL				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=20]	53183 (\pm 26877)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=16]	54963 (\pm 29531)			

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of Cephalexin Administered With and Without Gilteritinib

End point title	Tmax of Cephalexin Administered With and Without
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 1.5, 2, 3, 4, 6, 24 hours postdose (cephalexin)

Notes:

[62] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: hours				
median (full range (min-max))				
Cephalexin Alone (Day -1) [N=20]	1.500 (1.00 to 4.02)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=16]	1.483 (1.00 to 5.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: T1/2 of Cephalexin Administered With and Without Gilteritinib

End point title	T1/2 of Cephalexin Administered With and Without
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 1.5, 2, 3, 4, 6, 24 hours postdose (cephalexin)

Notes:

[63] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: hours				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=20]	1.822 (± 0.5914)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=16]	1.827 (± 0.7175)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Total Systemic Clearance After Single or Multiple Extravascular Dosing (CL/F) of Cephalexin Administered With and Without Gilteritinib

End point title	Apparent Total Systemic Clearance After Single or Multiple Extravascular Dosing (CL/F) of Cephalexin Administered With and Without Gilteritinib ^[64]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 1.5, 2, 3, 4, 6, 24 hours postdose (cephalexin)

Notes:

[64] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: L/h				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=18]	9.713 (± 3.319)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=13]	10.58 (± 2.977)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution During the Terminal Elimination Phase After Single Extravascular Dosing (V_z/F) of Cephalexin Administered With and Without Gilteritinib

End point title	Apparent Volume of Distribution During the Terminal Elimination Phase After Single Extravascular Dosing (V _z /F) of Cephalexin Administered With and Without Gilteritinib ^[65]
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End point description:

Plasma samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: predose, 0.5, 1, 1.5, 2, 3, 4, 6, 24 hours postdose (cephalexin)

Notes:

[65] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: liters				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=18]	24.07 (± 7.173)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=13]	25.86 (± 5.346)			

Statistical analyses

No statistical analyses for this end point

Secondary: Amount of Drug Excreted in Urine (Aelast) of Cephalexin Administered With and Without Gilteritinib

End point title	Amount of Drug Excreted in Urine (Aelast) of Cephalexin Administered With and Without Gilteritinib ^[66]
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End point description:

Urine samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: 0-3 hours, 3-6 hours, 6-24 hours postdose (cephalexin)

Notes:

[66] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: mg				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=13]	548.9 (± 523.7)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=10]	448.8 (± 306.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Fraction of Drug Excreted into Urine in Percentage (%Ae) of Cephalexin Administered With and Without Gilteritinib

End point title	Fraction of Drug Excreted into Urine in Percentage (%Ae) of Cephalexin Administered With and Without Gilteritinib ^[67]
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End point description:

Urine samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: 0-3 hours, 3-6 hours, 6-24 hours postdose (cephalexin)

Notes:

[67] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: percentage				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=13]	109.8 (± 104.7)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=10]	89.75 (± 61.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Renal Clearance (CLr) of Cephalexin in Administered With and Without Gilteritinib

End point title	Renal Clearance (CLr) of Cephalexin in Administered With and Without Gilteritinib ^[68]
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End point description:

Urine samples were used for pharmacokinetic assessments. The analysis population was the PKAS, with participants administered 200 mg gilteritinib and cephalexin.

End point type	Secondary
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End point timeframe:

Day -1 and cycle 1 day 15: 0-3 hours, 3-6 hours, 6-24 hours postdose (cephalexin)

Notes:

[68] - 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: Only participants administered with 200 mg gilteritinib and cephalexin are applicable to this endpoint.

End point values	Gilteritinib 200 mg in Expansion Phase			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: L/h				
arithmetic mean (standard deviation)				
Cephalexin Alone (Day -1) [N=13]	8.784 (± 8.727)			
Cephalexin + Gilteritinib (Cycle 1 Day 15) [N=6]	11.04 (± 8.430)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug up to 30 days after last dose of study drug (median treatment duration was 69.5 days, minimum of 3 days and maximum of 1320 days)

Adverse event reporting additional description:

The analysis population was the safety analysis set (SAF), which consisted of all participants who received at least 1 dose of study drug and excluded re-enrolled participants. The total number of deaths (all causes) includes deaths reported after the time frame above.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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Reporting groups

Reporting group title	Gilteritinib 20 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 20 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 20 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 40 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 40 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 40 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 120 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 120 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 120 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 80 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 80 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 80 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 200 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 200 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 120 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 300 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 300 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 300 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 450 mg in Escalation Phase
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Reporting group description:

Participants received a single dose of 450 mg gilteritinib orally on day -2 to evaluate pharmacokinetics of gilteritinib. Then starting on day 1 of cycle 1, participants received 450 mg gilteritinib orally once daily in 28-day cycles until disease progression or participant discontinuation in the escalation phase of the study.

Reporting group title	Gilteritinib 20 mg in Expansion Phase
Reporting group description: Participants received 20 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. Starting on day 16 of cycle 1, participants also received 200 mg voriconazole orally every 12 hours through day 1 of cycle 2.	
Reporting group title	Gilteritinib 40 mg in Expansion Phase
Reporting group description: Participants received 40 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.	
Reporting group title	Gilteritinib 80 mg in Expansion Phase
Reporting group description: Participants received 80 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.	
Reporting group title	Gilteritinib 200 mg in Expansion Phase
Reporting group description: Participants received 200 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, certain participants also received 500 mg cephalexin as a single oral dose.	
Reporting group title	Gilteritinib 120 mg in Expansion Phase
Reporting group description: Participants received 120 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study.	
Reporting group title	Gilteritinib 300 mg in Expansion Phase
Reporting group description: Participants received 300 mg gilteritinib orally once daily starting on day 1 of cycle 1 and continued in 28-day cycles until disease progression or participant discontinuation in the expansion phase of the study. On day -1 and day 15 of cycle 1, participants also received 2 mg midazolam as a single oral dose.	

Serious adverse events	Gilteritinib 20 mg in Escalation Phase	Gilteritinib 40 mg in Escalation Phase	Gilteritinib 120 mg in Escalation Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
number of deaths (all causes)	4	2	3
number of deaths resulting from adverse events	2	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Basal cell carcinoma			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Central nervous system leukaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Leukaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Phlebitis deep			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Death			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Fatigue			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Sudden death			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Acute graft versus host disease in intestine			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Acute graft versus host disease in skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Anaphylactic reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Chronic graft versus host disease in skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Graft versus host disease in skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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

Aspiration				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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	
Epistaxis				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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	
Haemoptysis				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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	
Hypoxia				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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	
Laryngeal mass				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 infiltration				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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	
Pneumonitis				

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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 haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 distress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Mental status changes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Aspartate aminotransferase			

increased				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 bilirubin increased				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 creatine phosphokinase increased				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 creatinine increased				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 lactate dehydrogenase increased				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 uric acid increased				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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	
Ejection fraction decreased				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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	
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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	
Liver function test increased				

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Transaminases increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Troponin I increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
White blood cell count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hip fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pelvic fracture			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Road traffic accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Tendon rupture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Wound complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Atrial thrombosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Atrioventricular block second degree			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Myocarditis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pericardial effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pericarditis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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
Ventricular fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Coordination abnormal			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Haemorrhage intracranial			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (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
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Intracranial pressure increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Loss of consciousness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Posterior reversible encephalopathy syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Radicular pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Leukocytosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (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
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pancytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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
Eye disorders			
Conjunctival oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Papilloedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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			
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Diarrhoea			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Enteritis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Haematemesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Intestinal obstruction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Intestinal perforation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Large intestinal ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Malabsorption			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Neutropenic colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pancreatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pancreatitis acute			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Rectal tenesmus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Swollen tongue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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			
Cholecystitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Angioedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Rash papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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 failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 tubular necrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Endocrine disorders			
Diabetes insipidus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Joint effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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

Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Necrotising myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Osteonecrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Rhabdomyolysis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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			
Abscess limb			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Arthritis bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Bacteraemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (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
Bacterial infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Clostridial infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Clostridium bacteraemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Corona virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Diverticulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Encephalitis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Epiglottitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Escherichia sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Fungaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hepatic infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Klebsiella bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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
Oral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Osteomyelitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Otitis externa			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Periodontitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Periorbital infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (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 fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 haemophilus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 parainfluenzae viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 viral			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Post procedural cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pseudomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Sinusitis fungal			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Skin bacterial infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Streptococcal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Systemic candida			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Systemic mycosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Tooth abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Toxic shock syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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 / 5 (0.00%)	0 / 3 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Failure to thrive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Hyponatraemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (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	Gilterinib 80 mg in Escalation Phase	Gilterinib 200 mg in Escalation Phase	Gilterinib 300 mg in Escalation Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	2 / 3 (66.67%)
number of deaths (all causes)	3	2	3
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 1
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Central nervous system leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (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
Orthostatic hypotension			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Phlebitis deep			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oedema peripheral			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Acute graft versus host disease in intestine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Acute graft versus host disease in skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Anaphylactic reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Chronic graft versus host disease in skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Graft versus host disease in skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Epistaxis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Laryngeal mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 infiltration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 distress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 creatine phosphokinase increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 creatinine increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 lactate dehydrogenase increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 uric acid increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	
Ejection fraction decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	
Liver function test increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	
Platelet count decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	
Transaminases increased				

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pelvic fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Road traffic accident			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Tendon rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Wound complication			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Atrial thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Atrioventricular block second degree			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 arrest			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 failure congestive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pericarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Ventricular fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Coordination abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haemorrhage intracranial			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Intracranial pressure increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Loss of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Radicular pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	1 / 3 (33.33%)	2 / 3 (66.67%)	2 / 3 (66.67%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Neutropenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Eye disorders			
Conjunctival oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Papilloedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Enteritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Intestinal perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Large intestinal ulcer			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Malabsorption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Neutropenic colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Rectal tenesmus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Swollen tongue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hyperbilirubinaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Angioedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 tubular necrosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Endocrine disorders			
Diabetes insipidus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Joint effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Necrotising myositis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Osteonecrosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Arthritis bacterial			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Bacteraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Clostridial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Clostridium bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Clostridium difficile infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Corona virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Encephalitis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Enterococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Epiglottitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Fungaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hepatic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Klebsiella bacteraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Osteomyelitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Otitis externa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Periodontitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Periorbital infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pneumonia haemophilus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 parainfluenzae viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Post procedural cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pseudomonas infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 syncytial virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Sinusitis fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Skin bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Skin infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Streptococcal sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Systemic candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Systemic mycosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Tooth abscess			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Toxic shock syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Failure to thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	Gilterinib 450 mg in Escalation Phase	Gilterinib 20 mg in Expansion Phase	Gilterinib 40 mg in Expansion Phase
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Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	8 / 12 (66.67%)	12 / 13 (92.31%)
number of deaths (all causes)	3	10	13
number of deaths resulting from adverse events	1	3	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	3 / 13 (23.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 3
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis deep			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute graft versus host disease in intestine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute graft versus host disease in skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease in skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Laryngeal mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coordination abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radicular pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 12 (33.33%)	7 / 13 (53.85%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctival oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malabsorption			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal tenesmus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swollen tongue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	3 / 13 (23.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Diabetes insipidus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia parainfluenzae viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic mycosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic shock syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Gilterinib 80 mg in Expansion Phase	Gilterinib 200 mg in Expansion Phase	Gilterinib 120 mg in Expansion Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 21 (90.48%)	92 / 100 (92.00%)	52 / 66 (78.79%)
number of deaths (all causes)	21	82	53
number of deaths resulting from adverse events	11	49	23
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	5 / 21 (23.81%)	20 / 100 (20.00%)	9 / 66 (13.64%)
occurrences causally related to treatment / all	0 / 8	0 / 25	0 / 10
deaths causally related to treatment / all	0 / 5	0 / 16	0 / 9

Acute myeloid leukaemia recurrent subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (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
Basal cell carcinoma subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Leukaemia subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Squamous cell carcinoma subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders Deep vein thrombosis subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 21 (0.00%)	4 / 100 (4.00%)	3 / 66 (4.55%)
occurrences causally related to treatment / all	0 / 0	2 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Phlebitis deep			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (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
Death			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 21 (0.00%)	4 / 100 (4.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 1
Oedema peripheral			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Pyrexia			
subjects affected / exposed	0 / 21 (0.00%)	9 / 100 (9.00%)	9 / 66 (13.64%)
occurrences causally related to treatment / all	0 / 0	2 / 13	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Acute graft versus host disease			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute graft versus host disease in intestine			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Acute graft versus host disease in skin			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease in skin			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in skin			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (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 promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			

subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (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
Acute respiratory failure			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aspiration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (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
Haemoptysis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 21 (4.76%)	3 / 100 (3.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 1	1 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Laryngeal mass			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
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 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Pleural effusion			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 21 (4.76%)	11 / 100 (11.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 2	0 / 13	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 5	0 / 1
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			

subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	3 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood uric acid increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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

Ejection fraction decreased subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
White blood cell count increased subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Injury, poisoning and procedural complications			
Facial bones fracture subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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

Fall			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Subdural haematoma			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (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
Wound complication			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute myocardial infarction			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (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
Atrial fibrillation			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	3 / 66 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (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 arrest			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Myocarditis			

subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Ventricular tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Cerebral ischaemia			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Coordination abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Headache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Neuralgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radicular pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	5 / 100 (5.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	1 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 21 (4.76%)	4 / 100 (4.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Disseminated intravascular coagulation			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	5 / 21 (23.81%)	35 / 100 (35.00%)	18 / 66 (27.27%)
occurrences causally related to treatment / all	1 / 11	3 / 58	1 / 28
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemolytic anaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	1 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pancytopenia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctival oedema			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	5 / 66 (7.58%)
occurrences causally related to treatment / all	0 / 1	2 / 5	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	1 / 1	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Haematochezia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Intestinal perforation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal ulcer			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malabsorption			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Pancreatitis acute			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Rectal tenesmus			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Swollen tongue			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 21 (14.29%)	14 / 100 (14.00%)	5 / 66 (7.58%)
occurrences causally related to treatment / all	0 / 4	3 / 16	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
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 tubular necrosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Diabetes insipidus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Necrotising myositis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
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			
Abscess limb			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	5 / 21 (23.81%)	5 / 100 (5.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 9	1 / 7	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cellulitis			

subjects affected / exposed	0 / 21 (0.00%)	4 / 100 (4.00%)	4 / 66 (6.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Clostridial infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 21 (0.00%)	6 / 100 (6.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	1 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Diverticulitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Herpes zoster			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 21 (0.00%)	7 / 100 (7.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oral infection			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Otitis externa			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Periorbital infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 21 (9.52%)	12 / 100 (12.00%)	13 / 66 (19.70%)
occurrences causally related to treatment / all	0 / 2	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Pneumonia fungal			
subjects affected / exposed	0 / 21 (0.00%)	5 / 100 (5.00%)	5 / 66 (7.58%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia parainfluenzae viral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Pseudomonas infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Pyelonephritis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	7 / 21 (33.33%)	19 / 100 (19.00%)	10 / 66 (15.15%)
occurrences causally related to treatment / all	0 / 8	1 / 25	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 8	0 / 1
Septic shock			

subjects affected / exposed	3 / 21 (14.29%)	4 / 100 (4.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 6	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 3	0 / 0
Sinusitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis fungal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Streptococcal bacteraemia			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Systemic candida			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic mycosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Tooth infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Toxic shock syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	3 / 66 (4.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	2 / 21 (9.52%)	2 / 100 (2.00%)	3 / 66 (4.55%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (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
Failure to thrive			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Hyperuricaemia			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Hypocalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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
Hyponatraemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (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	Gilterinib 300 mg in Expansion Phase		
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 17 (82.35%)		
number of deaths (all causes)	16		
number of deaths resulting from adverse events	7		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	4 / 17 (23.53%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 4		
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Central nervous system leukaemia subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukaemia subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders Deep vein thrombosis subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolism subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			

subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phlebitis deep			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mucosal inflammation			

subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute graft versus host disease in intestine			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute graft versus host disease in			

skin				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic reaction				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic graft versus host disease in skin				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Graft versus host disease in skin				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute promyelocytic leukaemia differentiation syndrome				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspiration				

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal mass				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Pulmonary haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory distress			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase			

increased				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood uric acid increased				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ejection fraction decreased				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Platelet count decreased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transaminases increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Troponin I increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
White blood cell count increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound complication			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial thrombosis			

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocarditis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericarditis				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coordination abnormal			

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intracranial pressure increased				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lethargy				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuralgia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Posterior reversible encephalopathy syndrome				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radicular pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	4 / 17 (23.53%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Haemolytic anaemia			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Conjunctival oedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papilloedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematochezia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal perforation				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal ulcer				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malabsorption				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic colitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal tenesmus			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Stomatitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Swollen tongue			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic failure			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angioedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash papular			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin lesion			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			

subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Renal injury			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal tubular necrosis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Diabetes insipidus			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint effusion			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Muscular weakness				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Necrotising myositis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhabdomyolysis				

subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridial infection			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium bacteraemia			

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Corona virus infection				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis viral				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal bacteraemia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal infection				

subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterocolitis infectious				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epiglottitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fungaemia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic infection				

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Klebsiella bacteraemia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis externa				

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periodontitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periorbital infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia haemophilus				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia parainfluenzae viral				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural cellulitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonas infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinusitis fungal				

subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin bacterial infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal bacteraemia				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Streptococcal sepsis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic candida				

subjects affected / exposed	1 / 17 (5.88%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Systemic mycosis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth abscess				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxic shock syndrome				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection bacterial				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection enterococcal				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperuricaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypocalcaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour lysis syndrome			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Gilterinib 20 mg in Escalation Phase	Gilterinib 40 mg in Escalation Phase	Gilterinib 120 mg in Escalation Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	2 / 3 (66.67%)	3 / 3 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Local swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nodule			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Serositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Nipple pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysphonia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngeal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Sinus pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Product issues			
Device occlusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Transaminases increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Ultrasound liver abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Volume blood increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Weight decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Incision site pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Periorbital haemorrhage subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Procedural pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Stoma site pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Transfusion reaction			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Hyperaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Febrile neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperfibrinogenaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eye oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal exudates			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Vision blurred			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitreous detachment			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	1	1	2
Diarrhoea			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Oesophagitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral mucosal blistering			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue coated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood blister			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Ecchymosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eccrine squamous syringometaplasia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pigmentation disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Urinary retention subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Bone pain subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Flank pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Myopathy			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngitis fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lung infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Urinary tract infection bacterial subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Urinary tract infection enterococcal subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Fluid overload subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0
Fluid retention subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hyperphosphataemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hyperuricaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Gilterinib 80 mg in Escalation Phase	Gilterinib 200 mg in Escalation Phase	Gilterinib 300 mg in Escalation Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 3 (33.33%)	3 / 3 (100.00%)	1 / 3 (33.33%)
occurrences (all)	2	6	2
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Serositis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Immune system disorders Graft versus host disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Reproductive system and breast disorders Nipple pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Atelectasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 2
Dyspnoea subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Haemoptysis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngeal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Ultrasound liver abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Volume blood increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Lethargy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Febrile neutropenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperfibrinogenaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal exudates			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Retinal haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Gingival bleeding subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Gingival pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Melaena subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Mouth haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Mouth ulceration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Oesophagitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Oral mucosal blistering subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Oral pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Proctalgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0

Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Salivary hypersecretion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Tongue coated subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood blister subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0
Decubitus ulcer subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Drug eruption subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Dry skin			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eccrine squamous syringometaplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pigmentation disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Rash papular subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Skin lesion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Swelling face subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0
Renal and urinary disorders			
Dysuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Haematuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	2 / 3 (66.67%) 2
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Urinary retention subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Endocrine disorders			
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Back pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Myopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Laryngitis fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fluid overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypovolaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Iron overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Gilterinib 450 mg in Escalation Phase	Gilterinib 20 mg in Expansion Phase	Gilterinib 40 mg in Expansion Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	12 / 12 (100.00%)	12 / 13 (92.31%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hot flush			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	4 / 12 (33.33%)	5 / 13 (38.46%)
occurrences (all)	3	5	6
Gait disturbance			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Local swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	4 / 12 (33.33%)	2 / 13 (15.38%)
occurrences (all)	1	4	2
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	3 / 13 (23.08%)
occurrences (all)	0	1	3
Serositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Reproductive system and breast disorders Nipple pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
Respiratory, thoracic and mediastinal disorders Atelectasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 12 (16.67%) 3	1 / 13 (7.69%) 1
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 12 (25.00%) 4	5 / 13 (38.46%) 5
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	3 / 12 (25.00%) 3	3 / 13 (23.08%) 3
Haemoptysis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Hypoxia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	1 / 13 (7.69%) 1
Nasal congestion subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Oropharyngeal pain			

subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	2 / 13 (15.38%)
occurrences (all)	0	2	2
Pharyngeal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2

Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	4	3	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	2 / 13 (15.38%)
occurrences (all)	0	2	3
Blood creatine phosphokinase			

increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	2
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 12 (16.67%)	3 / 13 (23.08%)
occurrences (all)	1	8	4
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ultrasound liver abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Volume blood increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Fall			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Incision site pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Periorbital haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	2 / 13 (15.38%) 2
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Nervous system disorders			
Cognitive disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	1 / 13 (7.69%) 1
Dysaesthesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 12 (16.67%) 2	1 / 13 (7.69%) 1
Headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 12 (16.67%) 2	1 / 13 (7.69%) 1
Hyperaesthesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Lethargy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Memory impairment subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Neuropathy peripheral subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Paraesthesia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	4 / 13 (30.77%)
occurrences (all)	0	4	4
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Hyperfibrinogenaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Glaucoma			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Retinal exudates			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Abdominal tenderness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	2 / 13 (15.38%)
occurrences (all)	2	1	2
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1

Melaena			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Mouth haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	3 / 13 (23.08%)
occurrences (all)	0	1	3
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral mucosal blistering			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Tongue coated			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	2	0

Vomiting subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 12 (16.67%) 3	1 / 13 (7.69%) 1
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Blood blister subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
Drug eruption subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Ecchymosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Eccrine squamous syringometaplasia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Erythema multiforme			

subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
Photosensitivity reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pigmentation disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Myopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
Enterococcal bacteraemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Gingivitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
Herpes virus infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
Influenza subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Laryngitis fungal subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Lip infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Lung infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Pharyngitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 12 (8.33%) 2	0 / 13 (0.00%) 0

Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Fluid overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Hypocalcaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 12 (8.33%)	2 / 13 (15.38%)
occurrences (all)	1	1	2
Hypochloraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 12 (41.67%)	2 / 13 (15.38%)
occurrences (all)	0	9	3
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypophosphataemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypoproteinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Gilterinib 80 mg in Expansion Phase	Gilterinib 200 mg in Expansion Phase	Gilterinib 120 mg in Expansion Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 21 (95.24%)	97 / 100 (97.00%)	62 / 66 (93.94%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	2 / 66 (3.03%)
occurrences (all)	1	8	2
Hot flush			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences (all)	0	2	2
Hypertension			
subjects affected / exposed	1 / 21 (4.76%)	16 / 100 (16.00%)	7 / 66 (10.61%)
occurrences (all)	1	34	7
Hypotension			
subjects affected / exposed	3 / 21 (14.29%)	25 / 100 (25.00%)	10 / 66 (15.15%)
occurrences (all)	4	32	11
Orthostatic hypotension			
subjects affected / exposed	1 / 21 (4.76%)	8 / 100 (8.00%)	3 / 66 (4.55%)
occurrences (all)	2	8	3
Pallor			

subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 2	0 / 100 (0.00%) 0	1 / 66 (1.52%) 1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 21 (14.29%)	19 / 100 (19.00%)	6 / 66 (9.09%)
occurrences (all)	3	20	8
Chills			
subjects affected / exposed	1 / 21 (4.76%)	12 / 100 (12.00%)	5 / 66 (7.58%)
occurrences (all)	1	15	5
Face oedema			
subjects affected / exposed	2 / 21 (9.52%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences (all)	3	2	2
Fatigue			
subjects affected / exposed	8 / 21 (38.10%)	32 / 100 (32.00%)	27 / 66 (40.91%)
occurrences (all)	11	47	38
Gait disturbance			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Generalised oedema			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences (all)	0	2	1
Local swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	1 / 66 (1.52%)
occurrences (all)	1	5	2
Malaise			
subjects affected / exposed	0 / 21 (0.00%)	5 / 100 (5.00%)	2 / 66 (3.03%)
occurrences (all)	0	5	3
Mucosal inflammation			
subjects affected / exposed	0 / 21 (0.00%)	11 / 100 (11.00%)	7 / 66 (10.61%)
occurrences (all)	0	13	9
Nodule			

subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	1	0	2
Oedema			
subjects affected / exposed	3 / 21 (14.29%)	6 / 100 (6.00%)	3 / 66 (4.55%)
occurrences (all)	5	7	5
Oedema peripheral			
subjects affected / exposed	5 / 21 (23.81%)	31 / 100 (31.00%)	17 / 66 (25.76%)
occurrences (all)	11	48	22
Pain			
subjects affected / exposed	0 / 21 (0.00%)	6 / 100 (6.00%)	6 / 66 (9.09%)
occurrences (all)	0	9	7
Peripheral swelling			
subjects affected / exposed	1 / 21 (4.76%)	4 / 100 (4.00%)	3 / 66 (4.55%)
occurrences (all)	2	6	4
Pyrexia			
subjects affected / exposed	3 / 21 (14.29%)	24 / 100 (24.00%)	18 / 66 (27.27%)
occurrences (all)	3	33	25
Serositis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	3 / 66 (4.55%)
occurrences (all)	0	0	4
Seasonal allergy			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences (all)	1	1	1
Reproductive system and breast disorders			
Nipple pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Cough			

subjects affected / exposed	7 / 21 (33.33%)	26 / 100 (26.00%)	18 / 66 (27.27%)
occurrences (all)	7	29	27
Dysphonia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences (all)	0	2	1
Dyspnoea			
subjects affected / exposed	4 / 21 (19.05%)	28 / 100 (28.00%)	19 / 66 (28.79%)
occurrences (all)	5	38	23
Dyspnoea exertional			
subjects affected / exposed	1 / 21 (4.76%)	3 / 100 (3.00%)	6 / 66 (9.09%)
occurrences (all)	1	3	7
Epistaxis			
subjects affected / exposed	3 / 21 (14.29%)	20 / 100 (20.00%)	16 / 66 (24.24%)
occurrences (all)	3	24	18
Haemoptysis			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences (all)	0	2	2
Hypoxia			
subjects affected / exposed	2 / 21 (9.52%)	11 / 100 (11.00%)	5 / 66 (7.58%)
occurrences (all)	2	14	8
Nasal congestion			
subjects affected / exposed	3 / 21 (14.29%)	9 / 100 (9.00%)	3 / 66 (4.55%)
occurrences (all)	4	9	4
Oropharyngeal pain			
subjects affected / exposed	0 / 21 (0.00%)	8 / 100 (8.00%)	5 / 66 (7.58%)
occurrences (all)	0	11	6
Pharyngeal disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 21 (4.76%)	10 / 100 (10.00%)	2 / 66 (3.03%)
occurrences (all)	1	14	2
Rales			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences (all)	0	1	1
Rhinorrhoea			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Sinus pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	4 / 66 (6.06%)
occurrences (all)	0	3	4
Wheezing			
subjects affected / exposed	0 / 21 (0.00%)	5 / 100 (5.00%)	2 / 66 (3.03%)
occurrences (all)	0	6	2
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 21 (4.76%)	3 / 100 (3.00%)	0 / 66 (0.00%)
occurrences (all)	1	3	0
Anxiety			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	5 / 66 (7.58%)
occurrences (all)	1	6	5
Confusional state			
subjects affected / exposed	3 / 21 (14.29%)	10 / 100 (10.00%)	4 / 66 (6.06%)
occurrences (all)	3	12	4
Depression			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	3 / 66 (4.55%)
occurrences (all)	1	6	3
Disorientation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	3 / 21 (14.29%)	13 / 100 (13.00%)	8 / 66 (12.12%)
occurrences (all)	3	14	9
Mental status changes			
subjects affected / exposed	2 / 21 (9.52%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	2	2	0

Sleep disorder subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 2	0 / 100 (0.00%) 0	0 / 66 (0.00%) 0
Product issues Device occlusion subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 100 (0.00%) 0	0 / 66 (0.00%) 0
Investigations Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	4 / 100 (4.00%) 5	1 / 66 (1.52%) 1
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 9	25 / 100 (25.00%) 46	16 / 66 (24.24%) 26
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 9	35 / 100 (35.00%) 61	20 / 66 (30.30%) 33
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 12	15 / 100 (15.00%) 19	10 / 66 (15.15%) 12
Blood bilirubin increased subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 3	12 / 100 (12.00%) 22	1 / 66 (1.52%) 1
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	15 / 100 (15.00%) 27	5 / 66 (7.58%) 9
Blood creatinine increased subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 9	19 / 100 (19.00%) 40	13 / 66 (19.70%) 23
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	7 / 100 (7.00%) 9	3 / 66 (4.55%) 4
Blood phosphorus decreased			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
Cardiac murmur			
subjects affected / exposed	2 / 21 (9.52%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	2	0	1
Chest X-ray abnormal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 21 (4.76%)	9 / 100 (9.00%)	9 / 66 (13.64%)
occurrences (all)	1	11	13
International normalised ratio increased			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	4 / 66 (6.06%)
occurrences (all)	1	7	7
Liver function test increased			
subjects affected / exposed	1 / 21 (4.76%)	3 / 100 (3.00%)	1 / 66 (1.52%)
occurrences (all)	2	4	1
Neutrophil count decreased			
subjects affected / exposed	1 / 21 (4.76%)	14 / 100 (14.00%)	8 / 66 (12.12%)
occurrences (all)	1	29	16
Platelet count decreased			
subjects affected / exposed	1 / 21 (4.76%)	17 / 100 (17.00%)	12 / 66 (18.18%)
occurrences (all)	1	37	26
Transaminases increased			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	5 / 66 (7.58%)
occurrences (all)	1	6	5
Ultrasound liver abnormal			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Volume blood increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 21 (0.00%)	6 / 100 (6.00%)	3 / 66 (4.55%)
occurrences (all)	0	7	3
Weight increased			
subjects affected / exposed	0 / 21 (0.00%)	12 / 100 (12.00%)	2 / 66 (3.03%)
occurrences (all)	0	18	5
White blood cell count decreased			
subjects affected / exposed	0 / 21 (0.00%)	13 / 100 (13.00%)	4 / 66 (6.06%)
occurrences (all)	0	30	14
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	3 / 21 (14.29%)	10 / 100 (10.00%)	3 / 66 (4.55%)
occurrences (all)	3	11	3
Fall			
subjects affected / exposed	2 / 21 (9.52%)	18 / 100 (18.00%)	11 / 66 (16.67%)
occurrences (all)	2	22	15
Incision site pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	0 / 66 (0.00%)
occurrences (all)	0	5	0
Periorbital haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
Post procedural haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
Procedural pain			

subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences (all)	0	1	1
Stoma site pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	3 / 66 (4.55%)
occurrences (all)	1	1	3
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
Atrial fibrillation			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	3 / 66 (4.55%)
occurrences (all)	1	5	3
Atrial flutter			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	2 / 21 (9.52%)	3 / 100 (3.00%)	0 / 66 (0.00%)
occurrences (all)	2	3	0
Pericardial effusion			
subjects affected / exposed	1 / 21 (4.76%)	3 / 100 (3.00%)	1 / 66 (1.52%)
occurrences (all)	1	3	1
Sinus bradycardia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	1	2	0
Sinus tachycardia			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	2 / 66 (3.03%)
occurrences (all)	2	7	2
Tachycardia			
subjects affected / exposed	1 / 21 (4.76%)	12 / 100 (12.00%)	1 / 66 (1.52%)
occurrences (all)	1	13	1
Nervous system disorders			
Cognitive disorder			

subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
Dizziness			
subjects affected / exposed	5 / 21 (23.81%)	26 / 100 (26.00%)	17 / 66 (25.76%)
occurrences (all)	6	34	19
Dysaesthesia			
subjects affected / exposed	0 / 21 (0.00%)	9 / 100 (9.00%)	4 / 66 (6.06%)
occurrences (all)	0	10	6
Dysgeusia			
subjects affected / exposed	1 / 21 (4.76%)	11 / 100 (11.00%)	9 / 66 (13.64%)
occurrences (all)	1	12	9
Headache			
subjects affected / exposed	3 / 21 (14.29%)	14 / 100 (14.00%)	10 / 66 (15.15%)
occurrences (all)	4	20	14
Hyperaesthesia			
subjects affected / exposed	0 / 21 (0.00%)	4 / 100 (4.00%)	2 / 66 (3.03%)
occurrences (all)	0	4	2
Lethargy			
subjects affected / exposed	2 / 21 (9.52%)	3 / 100 (3.00%)	1 / 66 (1.52%)
occurrences (all)	2	3	1
Memory impairment			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	7 / 66 (10.61%)
occurrences (all)	1	6	9
Paraesthesia			
subjects affected / exposed	0 / 21 (0.00%)	7 / 100 (7.00%)	6 / 66 (9.09%)
occurrences (all)	0	12	7
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 21 (0.00%)	7 / 100 (7.00%)	3 / 66 (4.55%)
occurrences (all)	0	8	3
Sciatica			

subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 100 (0.00%) 0	0 / 66 (0.00%) 0
Somnolence subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	2 / 100 (2.00%) 2	1 / 66 (1.52%) 1
Syncope subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	6 / 100 (6.00%) 6	2 / 66 (3.03%) 3
Tremor subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	6 / 100 (6.00%) 7	1 / 66 (1.52%) 2
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	7 / 21 (33.33%) 10	33 / 100 (33.00%) 65	27 / 66 (40.91%) 84
Febrile neutropenia subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	15 / 100 (15.00%) 20	7 / 66 (10.61%) 8
Hyperfibrinogenaemia subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 100 (0.00%) 0	0 / 66 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	4 / 100 (4.00%) 6	4 / 66 (6.06%) 4
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 100 (0.00%) 0	1 / 66 (1.52%) 1
Neutropenia subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	12 / 100 (12.00%) 29	5 / 66 (7.58%) 28
Thrombocytopenia subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 6	19 / 100 (19.00%) 44	12 / 66 (18.18%) 27
Ear and labyrinth disorders Ear discomfort			

subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	0 / 66 (0.00%)
occurrences (all)	0	3	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	4 / 66 (6.06%)
occurrences (all)	0	2	4
Cataract			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	4 / 66 (6.06%)
occurrences (all)	0	0	6
Cataract nuclear			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	4 / 21 (19.05%)	3 / 100 (3.00%)	0 / 66 (0.00%)
occurrences (all)	4	3	0
Dry eye			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	8 / 66 (12.12%)
occurrences (all)	1	7	10
Eye oedema			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences (all)	0	1	1
Glaucoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	2 / 66 (3.03%)
occurrences (all)	0	0	3
Periorbital oedema			
subjects affected / exposed	2 / 21 (9.52%)	5 / 100 (5.00%)	3 / 66 (4.55%)
occurrences (all)	2	9	3

Retinal exudates			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	3 / 66 (4.55%)
occurrences (all)	0	0	3
Vision blurred			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	5 / 66 (7.58%)
occurrences (all)	1	6	8
Vitreous detachment			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	4 / 66 (6.06%)
occurrences (all)	0	3	4
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 21 (0.00%)	7 / 100 (7.00%)	1 / 66 (1.52%)
occurrences (all)	0	8	1
Abdominal pain			
subjects affected / exposed	1 / 21 (4.76%)	15 / 100 (15.00%)	5 / 66 (7.58%)
occurrences (all)	1	19	6
Abdominal pain lower			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	3 / 66 (4.55%)
occurrences (all)	0	1	3
Abdominal tenderness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Colitis			

subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences (all)	0	2	2
Constipation			
subjects affected / exposed	5 / 21 (23.81%)	32 / 100 (32.00%)	12 / 66 (18.18%)
occurrences (all)	5	36	14
Diarrhoea			
subjects affected / exposed	5 / 21 (23.81%)	45 / 100 (45.00%)	27 / 66 (40.91%)
occurrences (all)	12	71	44
Dry mouth			
subjects affected / exposed	2 / 21 (9.52%)	10 / 100 (10.00%)	4 / 66 (6.06%)
occurrences (all)	2	10	4
Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	3 / 66 (4.55%)
occurrences (all)	0	3	3
Dysphagia			
subjects affected / exposed	0 / 21 (0.00%)	7 / 100 (7.00%)	2 / 66 (3.03%)
occurrences (all)	0	8	2
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	4 / 100 (4.00%)	0 / 66 (0.00%)
occurrences (all)	1	5	0
Gingival bleeding			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences (all)	1	2	2
Gingival pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences (all)	0	1	1
Haemorrhoids			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	1 / 66 (1.52%)
occurrences (all)	1	8	1
Melaena			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	1	1	0
Mouth haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	8 / 100 (8.00%)	2 / 66 (3.03%)
occurrences (all)	1	9	2
Mouth ulceration			

subjects affected / exposed	1 / 21 (4.76%)	4 / 100 (4.00%)	4 / 66 (6.06%)
occurrences (all)	1	5	5
Nausea			
subjects affected / exposed	4 / 21 (19.05%)	28 / 100 (28.00%)	15 / 66 (22.73%)
occurrences (all)	5	37	22
Oesophagitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences (all)	0	1	1
Oral mucosal blistering			
subjects affected / exposed	2 / 21 (9.52%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences (all)	2	3	2
Oral pain			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences (all)	0	3	1
Proctalgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	4 / 100 (4.00%)	1 / 66 (1.52%)
occurrences (all)	0	4	1
Salivary hypersecretion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 21 (0.00%)	14 / 100 (14.00%)	8 / 66 (12.12%)
occurrences (all)	0	15	9
Tongue coated			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	5 / 21 (23.81%)	22 / 100 (22.00%)	13 / 66 (19.70%)
occurrences (all)	6	31	16
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	2 / 21 (9.52%)	6 / 100 (6.00%)	2 / 66 (3.03%)
occurrences (all)	2	12	2

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	5 / 66 (7.58%)
occurrences (all)	0	0	6
Blood blister			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences (all)	0	2	1
Decubitus ulcer			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences (all)	1	3	1
Dermatitis acneiform			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	1 / 21 (4.76%)	4 / 100 (4.00%)	5 / 66 (7.58%)
occurrences (all)	1	4	5
Dry skin			
subjects affected / exposed	2 / 21 (9.52%)	3 / 100 (3.00%)	3 / 66 (4.55%)
occurrences (all)	4	5	3
Ecchymosis			
subjects affected / exposed	2 / 21 (9.52%)	8 / 100 (8.00%)	3 / 66 (4.55%)
occurrences (all)	3	8	3
Eccrine squamous syringometaplasia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	2 / 21 (9.52%)	4 / 100 (4.00%)	3 / 66 (4.55%)
occurrences (all)	2	4	4
Erythema multiforme			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	3 / 21 (14.29%)	4 / 100 (4.00%)	1 / 66 (1.52%)
occurrences (all)	4	4	1
Pain of skin			

subjects affected / exposed	0 / 21 (0.00%)	5 / 100 (5.00%)	1 / 66 (1.52%)
occurrences (all)	0	5	1
Petechiae			
subjects affected / exposed	0 / 21 (0.00%)	14 / 100 (14.00%)	0 / 66 (0.00%)
occurrences (all)	0	14	0
Photosensitivity reaction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	1 / 66 (1.52%)
occurrences (all)	0	1	1
Pigmentation disorder			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	2 / 21 (9.52%)	7 / 100 (7.00%)	0 / 66 (0.00%)
occurrences (all)	2	12	0
Rash			
subjects affected / exposed	0 / 21 (0.00%)	11 / 100 (11.00%)	11 / 66 (16.67%)
occurrences (all)	0	13	11
Rash maculo-papular			
subjects affected / exposed	1 / 21 (4.76%)	7 / 100 (7.00%)	3 / 66 (4.55%)
occurrences (all)	1	9	3
Rash papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	1 / 66 (1.52%)
occurrences (all)	1	5	1
Swelling face			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	2 / 66 (3.03%)
occurrences (all)	0	0	2
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 21 (4.76%)	7 / 100 (7.00%)	3 / 66 (4.55%)
occurrences (all)	1	8	3
Haematuria			
subjects affected / exposed	1 / 21 (4.76%)	6 / 100 (6.00%)	3 / 66 (4.55%)
occurrences (all)	2	6	4

Pollakiuria subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	7 / 100 (7.00%) 7	0 / 66 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	4 / 100 (4.00%) 5	5 / 66 (7.58%) 6
Urinary retention subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 2	7 / 100 (7.00%) 8	0 / 66 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	3 / 100 (3.00%) 3	1 / 66 (1.52%) 1
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 4	16 / 100 (16.00%) 23	12 / 66 (18.18%) 15
Back pain subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 2	9 / 100 (9.00%) 11	8 / 66 (12.12%) 9
Bone pain subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	7 / 100 (7.00%) 7	1 / 66 (1.52%) 1
Flank pain subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	1 / 100 (1.00%) 1	0 / 66 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	1 / 21 (4.76%) 1	4 / 100 (4.00%) 4	3 / 66 (4.55%) 4
Muscular weakness subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	4 / 100 (4.00%) 4	7 / 66 (10.61%) 7
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 100 (0.00%) 0	1 / 66 (1.52%) 1
Musculoskeletal pain			

subjects affected / exposed	1 / 21 (4.76%)	7 / 100 (7.00%)	2 / 66 (3.03%)
occurrences (all)	1	7	2
Myalgia			
subjects affected / exposed	0 / 21 (0.00%)	12 / 100 (12.00%)	5 / 66 (7.58%)
occurrences (all)	0	14	5
Myopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	4 / 66 (6.06%)
occurrences (all)	0	3	5
Pain in extremity			
subjects affected / exposed	2 / 21 (9.52%)	11 / 100 (11.00%)	10 / 66 (15.15%)
occurrences (all)	3	15	13
Pain in jaw			
subjects affected / exposed	1 / 21 (4.76%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	1	0	1
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	2 / 21 (9.52%)	2 / 100 (2.00%)	3 / 66 (4.55%)
occurrences (all)	2	2	3
Candida infection			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	4 / 66 (6.06%)
occurrences (all)	0	2	4
Cellulitis			
subjects affected / exposed	2 / 21 (9.52%)	1 / 100 (1.00%)	5 / 66 (7.58%)
occurrences (all)	3	1	6
Clostridium difficile infection			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	4 / 66 (6.06%)
occurrences (all)	1	2	4
Enterococcal bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	1 / 66 (1.52%)
occurrences (all)	0	2	1

Gingivitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 21 (0.00%)	5 / 100 (5.00%)	1 / 66 (1.52%)
occurrences (all)	0	5	1
Laryngitis fungal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Lung infection			
subjects affected / exposed	0 / 21 (0.00%)	5 / 100 (5.00%)	2 / 66 (3.03%)
occurrences (all)	0	5	2
Oral candidiasis			
subjects affected / exposed	1 / 21 (4.76%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	1	2	0
Oral herpes			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	1 / 66 (1.52%)
occurrences (all)	0	0	2
Pharyngitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	5 / 66 (7.58%)
occurrences (all)	2	6	6
Sinusitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences (all)	1	1	2

Skin infection			
subjects affected / exposed	1 / 21 (4.76%)	3 / 100 (3.00%)	3 / 66 (4.55%)
occurrences (all)	1	3	3
Upper respiratory tract infection			
subjects affected / exposed	1 / 21 (4.76%)	5 / 100 (5.00%)	7 / 66 (10.61%)
occurrences (all)	1	11	9
Urinary tract infection			
subjects affected / exposed	2 / 21 (9.52%)	5 / 100 (5.00%)	9 / 66 (13.64%)
occurrences (all)	2	7	9
Urinary tract infection bacterial			
subjects affected / exposed	1 / 21 (4.76%)	3 / 100 (3.00%)	4 / 66 (6.06%)
occurrences (all)	1	4	7
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 100 (1.00%)	0 / 66 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 21 (14.29%)	19 / 100 (19.00%)	11 / 66 (16.67%)
occurrences (all)	4	21	13
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	10 / 100 (10.00%)	1 / 66 (1.52%)
occurrences (all)	0	10	1
Fluid overload			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	2 / 66 (3.03%)
occurrences (all)	0	2	2
Fluid retention			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
Hypercalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 21 (0.00%)	14 / 100 (14.00%)	5 / 66 (7.58%)
occurrences (all)	0	16	7
Hyperkalaemia			

subjects affected / exposed	1 / 21 (4.76%)	9 / 100 (9.00%)	5 / 66 (7.58%)
occurrences (all)	2	10	6
Hyperphosphataemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 100 (1.00%)	2 / 66 (3.03%)
occurrences (all)	2	1	2
Hyperuricaemia			
subjects affected / exposed	0 / 21 (0.00%)	10 / 100 (10.00%)	4 / 66 (6.06%)
occurrences (all)	0	11	4
Hypoalbuminaemia			
subjects affected / exposed	4 / 21 (19.05%)	18 / 100 (18.00%)	7 / 66 (10.61%)
occurrences (all)	15	28	15
Hypocalcaemia			
subjects affected / exposed	3 / 21 (14.29%)	23 / 100 (23.00%)	11 / 66 (16.67%)
occurrences (all)	17	50	23
Hypochloraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 21 (0.00%)	3 / 100 (3.00%)	2 / 66 (3.03%)
occurrences (all)	0	4	2
Hypokalaemia			
subjects affected / exposed	2 / 21 (9.52%)	25 / 100 (25.00%)	10 / 66 (15.15%)
occurrences (all)	11	33	20
Hypomagnesaemia			
subjects affected / exposed	3 / 21 (14.29%)	17 / 100 (17.00%)	13 / 66 (19.70%)
occurrences (all)	3	25	19
Hyponatraemia			
subjects affected / exposed	2 / 21 (9.52%)	20 / 100 (20.00%)	8 / 66 (12.12%)
occurrences (all)	8	26	16
Hypophosphataemia			
subjects affected / exposed	1 / 21 (4.76%)	11 / 100 (11.00%)	6 / 66 (9.09%)
occurrences (all)	1	13	10
Hypoproteinaemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
Hypovolaemia			

subjects affected / exposed	0 / 21 (0.00%)	2 / 100 (2.00%)	0 / 66 (0.00%)
occurrences (all)	0	2	0
Iron overload			
subjects affected / exposed	0 / 21 (0.00%)	0 / 100 (0.00%)	4 / 66 (6.06%)
occurrences (all)	0	0	4

Non-serious adverse events	Gilteritinib 300 mg in Expansion Phase		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 17 (94.12%)		
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	2		
Hypotension			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Orthostatic hypotension			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pallor			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Chills			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Face oedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	4 / 17 (23.53%)		
occurrences (all)	4		
Gait disturbance			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Generalised oedema			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Local swelling			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Localised oedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Nodule			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Oedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	2		
Pain			

<p>subjects affected / exposed</p> <p>0 / 17 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Peripheral swelling</p> <p>subjects affected / exposed</p> <p>0 / 17 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Pyrexia</p> <p>subjects affected / exposed</p> <p>3 / 17 (17.65%)</p> <p>occurrences (all)</p> <p>3</p>			
<p>Serositis</p> <p>subjects affected / exposed</p> <p>0 / 17 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Immune system disorders</p> <p>Graft versus host disease</p> <p>subjects affected / exposed</p> <p>0 / 17 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Seasonal allergy</p> <p>subjects affected / exposed</p> <p>0 / 17 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Reproductive system and breast disorders</p> <p>Nipple pain</p> <p>subjects affected / exposed</p> <p>0 / 17 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Atelectasis</p> <p>subjects affected / exposed</p> <p>0 / 17 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>3 / 17 (17.65%)</p> <p>occurrences (all)</p> <p>3</p> <p>Dysphonia</p> <p>subjects affected / exposed</p> <p>1 / 17 (5.88%)</p> <p>occurrences (all)</p> <p>1</p> <p>Dyspnoea</p> <p>subjects affected / exposed</p> <p>2 / 17 (11.76%)</p> <p>occurrences (all)</p> <p>2</p> <p>Dyspnoea exertional</p>			

subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	4 / 17 (23.53%)		
occurrences (all)	4		
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pharyngeal disorder			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rales			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Sinus pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Tachypnoea			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Mental status changes			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Sleep disorder			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Product issues			
Device occlusion			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Investigations			

Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	3		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	2		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Blood phosphorus decreased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Blood urea increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Cardiac murmur			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Chest X-ray abnormal			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
International normalised ratio increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Liver function test increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Neutrophil count decreased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Transaminases increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Ultrasound liver abnormal			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Volume blood increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Weight increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Fall subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Incision site pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Periorbital haemorrhage subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1		
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Procedural pain subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1		
Stoma site pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Transfusion reaction subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1		
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Atrial fibrillation			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Atrial flutter			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pericardial effusion			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Sinus bradycardia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Headache			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

Hyperaesthesia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Memory impairment			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Paraesthesia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	6 / 17 (35.29%)		
occurrences (all)	6		
Febrile neutropenia			
subjects affected / exposed	3 / 17 (17.65%)		
occurrences (all)	3		
Hyperfibrinogenaemia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Leukocytosis			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Lymphadenopathy			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Thrombocytopenia			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Cataract			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Cataract nuclear			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Eye oedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Eye pruritus			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Glaucoma			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Periorbital oedema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Retinal exudates			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Retinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Vitreous detachment			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Vitreous floaters			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Abdominal pain lower			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Abdominal tenderness			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Colitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	5 / 17 (29.41%)		
occurrences (all)	6		
Dry mouth			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Dyspepsia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

Dysphagia			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Gingival bleeding			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Gingival pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Melaena			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Mouth haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Oesophagitis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Oral mucosal blistering			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Oral pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

Proctalgia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Salivary hypersecretion			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Tongue coated			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Blood blister			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Decubitus ulcer			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dermatitis acneiform			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Drug eruption			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Eccrine squamous syringometaplasia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Erythema multiforme			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pain of skin			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Petechiae			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Photosensitivity reaction			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pigmentation disorder			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rash			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rash papular			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Skin lesion			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	4		
Swelling face			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Urinary retention			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Myopathy			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

Pain in jaw subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Infections and infestations			
Abscess limb subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Bacteraemia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Candida infection subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Cellulitis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Enterococcal bacteraemia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1		
Gingivitis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Herpes virus infection subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Herpes zoster subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Influenza subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Laryngitis fungal			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Lip infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Lung infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Urinary tract infection bacterial			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Fluid overload			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Fluid retention			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyperphosphataemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	2		
Hypocalcaemia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		

Hypochloraemia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Hypophosphataemia			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Hypoproteinaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypovolaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Iron overload			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 July 2013	<p>The changes include:</p> <ul style="list-style-type: none">• Revised the first primary objective to determination of MTD rather than determination of DLT.• Added clarifying text to better describe the dose escalation cohort (Cohort 1) and the dose expansion cohort (Cohort 2), Schedule of Assessments, and Inpatient escalation and reduction.• Amended exclusion criteria No. 4 to read on-going grade 2 or greater toxicity from prior therapy would prohibit participation in this first-in-human-trial.• Amended exclusion criteria No. 5 to clarify that timing of the transplant is within 2 months from cycle 1 day 1. Added exclusion criteria No. 12 to respond to the lack of available pharmacokinetic data to determine potential pharmacodynamic drug interactions. Therefore, this exclusion criterion excludes patients treated with concomitant medications targeting serotonin 5-hydroxytryptamine receptor 1 (5HT1R) or 5-hydroxytryptamine 2B receptors (5HT2BRs) or sigma nonspecific receptors.• Added text prohibiting any other treatment AML during therapy with gilteritinib with the exception of hydroxyurea up to 2 g daily to keep the absolute blast count below 50000.• Amended the text regarding grade 3 nonhematologic toxicity, grade 3 nausea, and hematologic toxicity related to prolonged myelosuppression to include parameters of absolute neutrophil counts (ANC) < 500 for more than 21 days.• Provided clarification on the description of "no clinical benefit" to indicate patients will be taken off treatment if there is no clinical response after 2 cycles of therapy.• Removed the reference to a patient dosing diary for cycle 1.• Revised continuous reassessment method (CRM) to Bayesian logistic regression modeling throughout the protocol.• Primary endpoint was revised to reflect tolerability as the true endpoint, deleting text specific to determination of DLTs as the description of DLT is already outlined in the protocol.
16 July 2013	<p>The changes include(cont'd):</p> <ul style="list-style-type: none">• Added text identifying Cohort 1 as the escalation Cohort and the DLT observation period for this cohort is 30 days. Amended the Schedule of Assessments to include assessment of thyroid function studies as well as cycle 1 day 4 assessments for institutional standard of care lab testing. Added Interactive Response Technology (IRT) transaction dates and investigational product (IP) dispensing dates for when site visits include sending the patient home with IP.• The description of the study drug packaging and labeling was changed to reflect new configuration of 14 tablets per blister card.• Dose modification guidelines in Protocol Section 5.1.2 were further outlined to include hematologic toxicities and 2 tables were added. Protocol Table 7 was revised to describe Dose Reduction guidelines. Protocol Table 8 was developed to describe Dose Escalation guidelines.• Added thyroid function tests to the chemistry panel.• Protocol Appendix 12.1 describing the lists of prohibited medications was revised to include a nonexhaustive list of drugs targeting serotonin receptors and to provide guidance that a list of drugs that target sigma nonspecific receptor is not available, but that Investigators must be responsible for consulting drug label information when prescribing concomitant medications.• Updated the common serious AEs in AML by revising the list to include the events of pneumonia, sinusitis and bleeding hemorrhage.

21 January 2014	<p>The changes include(cont'd):</p> <ul style="list-style-type: none"> • Updated the instructions for missed doses and moved the instructions to the appropriate section in protocol. • Clarified the required assessments and frequency of assessments after a patient dose escalation event. • Clarified the Sponsor reporting requirements for treatment compliance deviations. • Removed reticulocyte parameter from the hematology panel. Updated bone marrow text to read aspirate and biopsy. Corrected tube size and type for phosphorylation samples. Corrected the coagulation tests being performed. Corrected tube size for chemistry and coagulation samples. • For visual acuity (VA) measurements, allow for the use of early treatment diabetic retinopathy study (ETDRS) or Snellen charts. • Updated the total blood volumes as listed in Section 5.8. • Corrected full analysis set (FAS) definition to read "The FAS will consist of all patients who are enrolled and receive at least 1 dose of study drug and who have at least 1 posttreatment data point. This will be the primary analysis set for efficacy analyses." • Added Ophthalmologic Assessment section to Analysis of Safety. • Clarified that individual patient data will be reviewed at the dose escalation meetings.
21 January 2014	<p>The changes include:</p> <ul style="list-style-type: none"> • Moved pharmacodynamic parameters from secondary to exploratory endpoints. Removed STAT5 and added S6 phosphorylation to pharmacodynamics parameters. Added event-free survival to secondary endpoints. • Study design was updated to allow changing to a modified 3 + 3 design and testing all dose levels based on the recommendation of the dose escalation committee's assessment of pharmacokinetic data. • Included additional patient replacement guidance to the protocol. • For pharmacokinetic, pharmacodynamic and PIA samples, added the following collection windows: <ul style="list-style-type: none"> o Predose – Within 30 minutes before drug administration o Post dose 0.5, 1, and 2 hours – Within \pm 10 minutes of nominal time o Post dose 4 and 6 hours – Within \pm 20 minutes of nominal time o Post dose 24 hours – Within \pm 90 minutes of nominal time • For ophthalmologic assessments, a \pm 3-day window for the procedure was added for all assessments after screening. • Changed the text 'Bone Marrow Aspiration or Biopsy' to 'Bone Marrow Aspiration and Biopsy' in the Protocol Schedule of Assessments, applicable footnotes and protocol text. • In Protocol Schedule of Assessments 2B and throughout the protocol, the CYP3A4 inhibitor, voriconazole (200 mg oral q 12 hours) was specified. In addition, voriconazole was to be provided by Astellas. • In Protocol Schedule of Assessments 2D and throughout the protocol, the dose and route (2 mg of syrup [1.0 mL] by mouth) for midazolam was specified. In addition, midazolam was to be provided by Astellas. • Updated the Protocol Table titles for 2B, 2C and 2D to be consistent with titles listed in Section 5.6.1 Pharmacokinetics. Added S6 Phosphorylation and removed STAT5. • Added information on AXL and its role in AML, with supporting literature to Introduction and Literature sections, respectively. • Added Cohort 1 instructions for use of the IRT system.
28 January 2014	<p>The changes include: The limit on the maximum dose of hydroxyurea that can be used was increased to 5 g, and the duration was limited to 2 weeks.</p>

19 May 2014	<p>The changes include (cont'd):</p> <ul style="list-style-type: none"> • Added text allowing patients that have a contraindication to voriconazole and/or midazolam to participate without the DDI component. • Added text allowing the voriconazole DDI study to be conducted at the next lowest dose level if the original dose level was closed before 12 patients participated in the DDI study. • Allowed for a Chest X-ray performed within 2 weeks of screening to be used to fulfill the screening requirement. • Added a footnote to the bone marrow biopsy, which allows for the procedure not to be repeated if collected within 2 weeks of the visit to the Protocol Posttreatment Schedule of Assessments. • Added a line item for the end of treatment IRT transaction to the Protocol Posttreatment Schedule of Assessments. • Added a \pm 1 day visit window for the weekly assessment visits after a patient dose escalation event. • Clarified that the initial 15 day restriction on CYP3A4 inhibitor use in Cohort 2 was limited to patients randomized to Protocol Table 2B: Schedule of Assessments with CYP3A4 inhibitor voriconazole and Protocol Table 2D: Schedule of Assessments with CYP3A4 induction study. • Amended protocol to allow gilteritinib to be available in 10, 40 and 100 mg tablets. Study drug in US continued to be packaged as blistered 10 and 100 mg tablets and incorporated 40 mg tablets provided in bottles. • Restricted Cohort 2 DDI study participation to US only.
07 July 2014	<p>The changes include:</p> <ul style="list-style-type: none"> • Updated the number of patients. • Further expanded select dose levels for efficacy evaluation. • Modified the allowable collection window for screening bone marrow to 21 days. • Modified the rescreening restrictions from the protocol to allow for up to 2 rescreenings of a patient. • Corrected inclusion criteria No. 5 by removing the waiting period for immunosuppression therapies.
23 September 2014	<p>The changes include:</p> <ul style="list-style-type: none"> • Modified the discontinuation criteria to allow patients experiencing clinical benefit but that have not achieved partial response or CRc to remain on treatment. • Allowed re-enrollment of patients who discontinued treatment for reasons other than toxicity or disease progression.
15 December 2014	<p>The changes include:</p> <ul style="list-style-type: none"> • Updated the number of patients to reflect the actual enrollment to Cohort 1 and an increase in the total number patients to be enrolled in the dose expansion for Cohort 2. • Revised required duration for birth control and ova donation for women from 30 days to 45 days and birth control and semen donation for men from 90 to 105 days. • Restricted the use of strong inhibitors or inducers of P-glycoprotein (P-gp) and MATE1, and added precautions around concomitant use of substrates of other CYP enzymes, P-gp and breast cancer resistance protein. • Allowed patients to resume treatment with gilteritinib after hematopoietic stem cell transplant (HSCT). • Added safety data from an interim analysis of Study 2215-CL-0101 to the protocol. • Removed the restriction that allowed Cohort 2 patients to dose escalate only once. • Updated protocol to require discussion with the Medical Monitor before resumption of treatment for patients who have drug interruptions of greater than 15 days for events unrelated to study drug. • Added aldolase to the chemistry panel for the central laboratory. • Included language that additional testing for metabolites of gilteritinib may be performed.

26 May 2015	<p>The changes include:</p> <ul style="list-style-type: none"> • Added MATE1 Substrate Drug-drug Interaction Substudy for US sites only. • Removed electroretinography examination. • Updated safety data from an interim analysis of Study 2215-CL-0101 to the protocol. • Required patients in CRc to only have bone marrow collections every 3 cycles for 1 year following study start. After that, bone marrow were only required as clinically indicated and at end of study. • Changed definition of red blood cell (RBC) transfusion independence from 4 weeks without infusion to 1 week.
18 August 2015	<p>The changes include:</p> <ul style="list-style-type: none"> • Removed statement requiring 15 evaluable patients to be enrolled in the Cohort 2 MATE1 substudy. • Three new exclusion criteria were added related to screening electrocardiogram (ECG) and laboratory results: <ul style="list-style-type: none"> o Exclusion criteria number 11 was added to exclude patients with mean Fridericia-corrected QT interval (QTcF) > 450 msec at screening based on central reading. o Exclusion criteria number 12 was added to exclude patients with long corrected QT interval (QTc) syndrome at screening. o Exclusion criteria number 13 was added to exclude patients with hypokalemia and hypomagnesemia at screening (defined as values below the lower limit of normal [LLN]). • Added a confirmatory ECG to be performed on day 9 and an Investigator assessment to consider a dose reduction for a patient if the mean QTcF for a patient from day 1 to day 8 has increased > 30 msec with no other known etiology. • Clarified that the mean QTcF of the triplicate ECG tracings based on central reading would be used for all treatment decisions. • Added a criterion to the dose medication modification category: Consider reducing dose of gilteritinib if the mean QTcF from day 1 to day 8 has increased > 30 msec and this is confirmed on day 9 and without any other etiology. • Revised dose reduction criteria related to grade 3 events related to gilteritinib.
02 June 2017	<p>The changes include:</p> <ul style="list-style-type: none"> • Revised study design: <ul style="list-style-type: none"> o Subjects who were receiving ASP2215 treatment and did not meet any 2215- CL-0101 discontinuation criteria may have been eligible to continue to receive ASP2215 treatment in a rollover study, 2215-CL-0109. o Subjects who chose not to participate or were not eligible for Study 2215-CL-0109 completed their participation in Study 2215-CL-0101 by completing the End of Treatment follow-up visit upon activation of Study 2215-CL-0109 at the institution. o Subjects in Study 2215-CL-0101 who were being followed for Long-term Follow-up at the time of study closure will be discontinued from any further follow-up. • Concomitant medication guidelines were updated to exclude strong inducers of cytochrome P450 (CYP) 3A, strong inhibitors or inducers of P-gp and drugs that target 5HT1R and 5HT2BR receptors. Drugs known to prolong QT or QTc intervals should be used with caution. Updated list of excluded concomitant medications. • Updated contact details of key sponsor's personnel. • Updated the study period to current planned end date of 2017. • Three inclusion criteria were updated related to pregnancy and contraception: <ul style="list-style-type: none"> o For female subjects the period after study participation during which the subject cannot become pregnant or donate ova was lengthened from 45 days to 180 days and for breastfeeding was lengthened from 45 days to 60 days. o For male subjects the period after study participation during which the subject must use contraception and not donate sperm was lengthened from 105 days to 120 days. o For female subjects and female partners of male subjects, pregnancy reporting was lengthened from 90 to 180 days from the discontinuation of dosing. • Minor administrative-type changes, e.g., typos, format, numbering, consistency were made throughout the protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported