Clinical trial results:
A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies (FIGHT-101)

Summary

EudraCT number	2016-002831-14
Trial protocol	DK
Global end of trial date	17 December 2021

Results information

Result version number	v2 (current)
This version publication date	26 January 2023
First version publication date	15 December 2022
Version creation reason	• Correction of full data set Revisions made to align with changes made to ClinicalTrials.gov results summary.

Trial information

Trial identification

Sponsor protocol code	INCB 54828-101

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the safety, tolerability, and pharmacological activity of pemigatinib in participants with advanced malignancies. This study was conducted in three parts: dose escalation (Part 1), dose expansion (Part 2), and combination therapy (Part 3).

Protection of trial subjects:

This study was to be performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, Good Clinical Practices as defined in Title 21 of the United States Code of Federal Regulations Parts 50, 54 56, 312, and Part 11 as well as International Council for Harmonisation Good Clinical Practice (ICH GCP) consolidated guidelines (E6) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 February 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 199
Country: Number of subjects enrolled	Denmark: 2
Worldwide total number of subjects	201
EEA total number of subjects	2

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	127
From 65 to 84 years	73

85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted at 15 sites: 14 in the United States; 1 in Denmark. The study was conducted in 3 parts. Participants self-administered once daily doses of pemigatinib on a 2-weeks-on/1-week-off therapy (intermittent) or continuous schedule. Participants also self-administered twice daily doses of pemigatinib on a continuous schedule.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: Intermittent pemigatinib 1/2/4 mg QD

Arm description:

Participants self-administered oral pemigatinib 1/2/4 milligrams (mg) once daily (QD) on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Intermittent pemigatinib 6 mg QD

Arm description:

Participants self-administered oral pemigatinib 6 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Intermittent pemigatinib 9 mg QD

Arm description:

Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Arm type	Experimental

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Intermittent pemigatinib 13.5 mg QD

Arm description:

Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Intermittent pemigatinib 20 mg QD

Arm description:

Participants self-administered oral pemigatinib 20 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Continuous pemigatinib 9 mg QD

Arm description:

Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Continuous pemigatinib 13.5 mg QD

Arm description:

Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Arm type	Experimental

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Continuous pemigatinib 20 mg QD

Arm description:

Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Continuous pemigatinib 7.5 mg BID

Arm description:

Participants self-administered oral pemigatinib 7.5 mg twice daily (BID) on Days 1 through 21 of each 21-day cycle.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 1: Continuous pemigatinib 10 mg BID

Arm description:

Participants self-administered oral pemigatinib 10 mg BID on Days 1 through 21 of each 21-day cycle.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 2: Intermittent pemigatinib 9 mg QD

Arm description:

Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Arm type	Experimental

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 2: Intermittent pemigatinib 13.5 mg QD

Arm description:

Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 2: Continuous pemigatinib 9 mg QD

Arm description:

Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 2: Continuous pemigatinib 13.5 mg QD

Arm description:

Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Arm title	Part 2: Continuous pemigatinib 20 mg QD

Arm description:

Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

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

Dosage and administration details: QD or BID intermittent or continuous dosing	

Arm title	Part 3: Gem/Cis/intermittent pemigatinib 9 mg

Arm description:

Participants received gemcitabine (Gem) intravenously starting at 1000 mg/meters squared (m^2) on Days 1 and 8 of each 21-day cycle. Cisplatin (Cis) was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin.

Arm type	Experimental
Investigational medicinal product name	gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 1000 mg/m^2 on Days 1 and 8 of each 21-day cycle	
Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle	
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: QD or BID intermittent or continuous dosing	

Arm title	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg

Arm description:

Participants received gemcitabine intravenously starting at 1000 mg/m^2 on Days 1 and 8 of each 21-day cycle. Cisplatin was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin.

Arm type	Experimental
Investigational medicinal product name	gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details: 1000 mg/m^2 on Days 1 and 8 of each 21-day cycle	
Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle	
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: QD or BID intermittent or continuous dosing	
Arm title	Part 3: Tras/intermittent pemigatinib 13.5 mg

Arm description:

Trastuzumab (Tras) was administered as an open-label, commercial product at an initial intravenous dose of 8 mg/kilograms (kg), followed by 6 mg/kg intravenously once every 3 weeks. The dose could have been adjusted for toxicity management, per commercial labeling. The investigator could have interrupted, modified, or discontinued trastuzumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of trastuzumab.

Arm type	Experimental
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: QD or BID intermittent or continuous dosing	
Investigational medicinal product name	trastuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 8 mg/kg initial dose followed by 6 mg/kg Q3W	
Arm title	Part 3: Doc/intermittent pemigatinib 13.5 mg

Arm description:

Participants received docetaxel (Doc) intravenously starting at 75 mg/m^2 once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of docetaxel.

Arm type	Experimental

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Investigational medicinal product name	docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

75 mg/m^2 Q3W

Arm title	Part 3: Pem/intermittent pemigatinib 9 mg

Arm description:

Participants received pembrolizumab (Pem) intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

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

Dosage and administration details:

QD or BID intermittent or continuous dosing

Investigational medicinal product name	pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W

Arm title	Part 3: Pem/intermittent pemigatinib 13.5 mg

Arm description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Arm type	Experimental
Investigational medicinal product name	pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details: 200 mg Q3W	
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: QD or BID intermittent or continuous dosing	
Arm title	Part 3: Pem/continuous pemigatinib 13.5 mg

Arm description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Arm type	Experimental
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: QD or BID intermittent or continuous dosing	
Investigational medicinal product name	pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 200 mg Q3W	
Arm title	Part 3: Ref/continuous pemigatinib 9 mg

Arm description:

Retifanlimab (Ref) was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: QD or BID intermittent or continuous dosing	
Investigational medicinal product name	retifanlimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 500 mg Q4W on a 28-day cycle	
Arm title	Part 3: Ref/continuous pemigatinib 13.5 mg

Arm description:	
Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.	
Arm type	Experimental
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
QD or BID intermittent or continuous dosing	
Investigational medicinal product name	retifanlimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
500 mg Q4W on a 28-day cycle	
Arm title	Part 3: Ref/continuous pemigatinib 20 mg
Arm description:	
Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.	
Arm type	Experimental
Investigational medicinal product name	pemigatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
QD or BID intermittent or continuous dosing	
Investigational medicinal product name	retifanlimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
500 mg Q4W on a 28-day cycle	

Number of subjects in period 1	Part 1: Intermittent pemigatinib 1/2/4 mg QD	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 9 mg QD
Started	3	4	3
Completed	0	0	0
Not completed	3	4	3
Adverse event, serious fatal	2	2	3
Placed on Hospice; Declined Further Follow-up	-	-	-
Consent withdrawn by subject	-	1	-

Clinical Decline; Withdrew by Physician	-	-	-
Adverse event, non-fatal	-	-	-
Rolled Over to Another Protocol	-	-	-
Study Terminated by Sponsor	-	-	-
Lost to follow-up	1	-	-
Disease Progression	-	1	-

Number of subjects in period 1	Part 1: Intermittent pemigatinib 13.5 mg QD	Part 1: Intermittent pemigatinib 20 mg QD	Part 1: Continuous pemigatinib 9 mg QD
Started	6	6	9
Completed	0	0	0
Not completed	6	6	9
Adverse event, serious fatal	6	6	6
Placed on Hospice; Declined Further Follow-up	-	-	-
Consent withdrawn by subject	-	-	1
Clinical Decline; Withdrew by Physician	-	-	-
Adverse event, non-fatal	-	-	-
Rolled Over to Another Protocol	-	-	-
Study Terminated by Sponsor	-	-	2
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 1: Continuous pemigatinib 13.5 mg QD	Part 1: Continuous pemigatinib 20 mg QD	Part 1: Continuous pemigatinib 7.5 mg BID
Started	10	9	4
Completed	1	1	0
Not completed	9	8	4
Adverse event, serious fatal	5	8	4
Placed on Hospice; Declined Further Follow-up	-	-	-
Consent withdrawn by subject	1	-	-
Clinical Decline; Withdrew by Physician	1	-	-
Adverse event, non-fatal	-	-	-
Rolled Over to Another Protocol	-	-	-
Study Terminated by Sponsor	2	-	-
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 1: Continuous pemigatinib 10 mg BID	Part 2: Intermittent pemigatinib 9 mg QD	Part 2: Intermittent pemigatinib 13.5 mg QD
Started	3	4	44

Completed	0	0	0
Not completed	3	4	44
Adverse event, serious fatal	2	3	29
Placed on Hospice; Declined Further Follow-up	-	-	-
Consent withdrawn by subject	-	-	13
Clinical Decline; Withdrew by Physician	-	-	-
Adverse event, non-fatal	-	-	-
Rolled Over to Another Protocol	-	-	-
Study Terminated by Sponsor	1	-	1
Lost to follow-up	-	-	-
Disease Progression	-	1	1

Number of subjects in period 1	Part 2: Continuous pemigatinib 9 mg QD	Part 2: Continuous pemigatinib 13.5 mg QD	Part 2: Continuous pemigatinib 20 mg QD
Started	5	20	6
Completed	0	0	1
Not completed	5	20	5
Adverse event, serious fatal	4	15	2
Placed on Hospice; Declined Further Follow-up	-	-	-
Consent withdrawn by subject	1	2	3
Clinical Decline; Withdrew by Physician	-	-	-
Adverse event, non-fatal	-	-	-
Rolled Over to Another Protocol	-	-	-
Study Terminated by Sponsor	-	3	-
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 3: Gem/Cis/intermittent pemigatinib 9 mg	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg
Started	1	7	6
Completed	0	0	0
Not completed	1	7	6
Adverse event, serious fatal	1	7	5
Placed on Hospice; Declined Further Follow-up	-	-	-
Consent withdrawn by subject	-	-	-
Clinical Decline; Withdrew by Physician	-	-	-
Adverse event, non-fatal	-	-	-
Rolled Over to Another Protocol	-	-	-
Study Terminated by Sponsor	-	-	1
Lost to follow-up	-	-	-

Disease Progression	-	-	-

Number of subjects in period 1	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg	Part 3: Pem/intermittent pemigatinib 13.5 mg
Started	7	3	14
Completed	0	0	0
Not completed	7	3	14
Adverse event, serious fatal	5	3	7
Placed on Hospice; Declined Further Follow-up	-	-	-
Consent withdrawn by subject	1	-	2
Clinical Decline; Withdrew by Physician	-	-	-
Adverse event, non-fatal	-	-	-
Rolled Over to Another Protocol	-	-	1
Study Terminated by Sponsor	1	-	1
Lost to follow-up	-	-	1
Disease Progression	-	-	2

Number of subjects in period 1	Part 3: Pem/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 9 mg	Part 3: Ref/continuous pemigatinib 13.5 mg
Started	9	7	9
Completed	0	0	1
Not completed	9	7	8
Adverse event, serious fatal	5	6	3
Placed on Hospice; Declined Further Follow-up	-	-	1
Consent withdrawn by subject	1	-	1
Clinical Decline; Withdrew by Physician	-	-	-
Adverse event, non-fatal	-	-	1
Rolled Over to Another Protocol	-	-	-
Study Terminated by Sponsor	1	1	2
Lost to follow-up	1	-	-
Disease Progression	1	-	-

Number of subjects in period 1	Part 3: Ref/continuous pemigatinib 20 mg
Started	2
Completed	1
Not completed	1
Adverse event, serious fatal	-
Placed on Hospice; Declined Further Follow-up	-
Consent withdrawn by subject	-
Clinical Decline; Withdrew by Physician	-

Adverse event, non-fatal	-
Rolled Over to Another Protocol	-
Study Terminated by Sponsor	1
Lost to follow-up	-
Disease Progression	-

Baseline characteristics

Reporting groups

Reporting group title	Part 1: Intermittent pemigatinib 1/2/4 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 1/2/4 milligrams (mg) once daily (QD) on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 1: Intermittent pemigatinib 6 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 6 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 1: Intermittent pemigatinib 9 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 1: Intermittent pemigatinib 13.5 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 1: Intermittent pemigatinib 20 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 20 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 1: Continuous pemigatinib 9 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 1: Continuous pemigatinib 13.5 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 1: Continuous pemigatinib 20 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 1: Continuous pemigatinib 7.5 mg BID

Reporting group description:

Participants self-administered oral pemigatinib 7.5 mg twice daily (BID) on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 1: Continuous pemigatinib 10 mg BID

Reporting group description:

Participants self-administered oral pemigatinib 10 mg BID on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 2: Intermittent pemigatinib 9 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 2: Intermittent pemigatinib 13.5 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 2: Continuous pemigatinib 9 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 2: Continuous pemigatinib 13.5 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 2: Continuous pemigatinib 20 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Gem/Cis/intermittent pemigatinib 9 mg

Reporting group description:

Participants received gemcitabine (Gem) intravenously starting at 1000 mg/meters squared (m^2) on Days 1 and 8 of each 21-day cycle. Cisplatin (Cis) was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin.

Reporting group title	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received gemcitabine intravenously starting at 1000 mg/m^2 on Days 1 and 8 of each 21-day cycle. Cisplatin was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin.

Reporting group title	Part 3: Tras/intermittent pemigatinib 13.5 mg

Reporting group description:

Trastuzumab (Tras) was administered as an open-label, commercial product at an initial intravenous dose of 8 mg/kilograms (kg), followed by 6 mg/kg intravenously once every 3 weeks. The dose could have been adjusted for toxicity management, per commercial labeling. The investigator could have interrupted, modified, or discontinued trastuzumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of trastuzumab.

Reporting group title	Part 3: Doc/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received docetaxel (Doc) intravenously starting at 75 mg/m^2 once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of docetaxel.

Reporting group title	Part 3: Pem/intermittent pemigatinib 9 mg

Reporting group description:

Participants received pembrolizumab (Pem) intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Pem/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor

approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Pem/continuous pemigatinib 13.5 mg

Reporting group description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Ref/continuous pemigatinib 9 mg

Reporting group description:

Retifanlimab (Ref) was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Ref/continuous pemigatinib 13.5 mg

Reporting group description:

Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Ref/continuous pemigatinib 20 mg

Reporting group description:

Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group values	Part 1: Intermittent pemigatinib 1/2/4 mg QD	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 9 mg QD
Number of subjects	3	4	3
Age categorical Units: Subjects			
Adults (18-64 years)	2	4	3
From 65-84 years	1	0	0
85 years and over	0	0	0
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years			
arithmetic mean	60.7	45.5	56.3
standard deviation	± 11.24	± 17.31	± 4.93
Sex: Female, Male Units: participants			
Female	2	2	2
Male	1	2	1
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	3	4	2
Black/African-American	0	0	1
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	0	0
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	3	3
Unknown or Not Reported	1	1	0

Reporting group values	Part 1: Intermittent pemigatinib 13.5 mg QD	Part 1: Intermittent pemigatinib 20 mg QD	Part 1: Continuous pemigatinib 9 mg QD
Number of subjects	6	6	9
Age categorical Units: Subjects			
Adults (18-64 years)	4	5	5
From 65-84 years	2	1	4
85 years and over	0	0	0
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years arithmetic mean standard deviation	59.0 ± 14.79	56.2 ± 11.89	57.9 ± 15.70
Sex: Female, Male Units: participants			
Female	3	3	6
Male	3	3	3
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	6	5	8
Black/African-American	0	1	0
Asian	0	0	1
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	2	1
Not Hispanic or Latino	6	4	8
Unknown or Not Reported	0	0	0

Reporting group values	Part 1: Continuous pemigatinib 13.5 mg QD	Part 1: Continuous pemigatinib 20 mg QD	Part 1: Continuous pemigatinib 7.5 mg BID
Number of subjects	10	9	4
Age categorical Units: Subjects			
Adults (18-64 years)	6	6	1
From 65-84 years	4	3	3
85 years and over	0	0	0
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years arithmetic mean standard deviation	61.2 ± 16.88	56.3 ± 15.19	66.8 ± 4.57

Sex: Female, Male Units: participants			
Female	5	6	0
Male	5	3	4
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	10	8	4
Black/African-American	0	0	0
Asian	0	1	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	9	9	4
Unknown or Not Reported	0	0	0

Reporting group values	Part 1: Continuous pemigatinib 10 mg BID	Part 2: Intermittent pemigatinib 9 mg QD	Part 2: Intermittent pemigatinib 13.5 mg QD
Number of subjects	3	4	44
Age categorical Units: Subjects			
Adults (18-64 years)	2	4	30
From 65-84 years	0	0	14
85 years and over	1	0	0
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years			
arithmetic mean	68.7	50.3	57.7
standard deviation	± 15.89	± 12.39	± 11.81
Sex: Female, Male Units: participants			
Female	2	3	27
Male	1	1	17
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	3	3	37
Black/African-American	0	0	7
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	4
Not Hispanic or Latino	3	3	39
Unknown or Not Reported	0	0	1

Reporting group values	Part 2: Continuous pemigatinib 9 mg QD	Part 2: Continuous pemigatinib 13.5 mg QD	Part 2: Continuous pemigatinib 20 mg QD

Number of subjects	5	20	6
Age categorical Units: Subjects			
Adults (18-64 years)	2	12	4
From 65-84 years	3	8	2
85 years and over	0	0	0
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years			
arithmetic mean	63.8	57.4	58.3
standard deviation	± 10.69	± 13.78	± 8.80
Sex: Female, Male Units: participants			
Female	5	10	5
Male	0	10	1
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	5	18	6
Black/African-American	0	0	0
Asian	0	1	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	4	0
Not Hispanic or Latino	5	16	6
Unknown or Not Reported	0	0	0

Reporting group values	Part 3: Gem/Cis/intermittent pemigatinib 9 mg	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg
Number of subjects	1	7	6
Age categorical Units: Subjects			
Adults (18-64 years)	1	7	5
From 65-84 years	0	0	1
85 years and over	0	0	0
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years			
arithmetic mean	61.0	54.1	47.8
standard deviation	± 9999	± 10.43	± 14.44
Sex: Female, Male Units: participants			
Female	0	3	4
Male	1	4	2
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	1	5	6
Black/African-American	0	1	0

Asian	0	1	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	1	7	6
Unknown or Not Reported	0	0	0

Reporting group values	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg	Part 3: Pem/intermittent pemigatinib 13.5 mg
Number of subjects	7	3	14
Age categorical Units: Subjects			
Adults (18-64 years)	5	2	5
From 65-84 years	2	1	9
85 years and over	0	0	0
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years			
arithmetic mean	62.4	55.0	64.7
standard deviation	± 9.16	± 15.72	± 10.50
Sex: Female, Male Units: participants			
Female	3	1	5
Male	4	2	9
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	6	2	10
Black/African-American	1	1	2
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	0	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	7	3	13
Unknown or Not Reported	0	0	0

Reporting group values	Part 3: Pem/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 9 mg	Part 3: Ref/continuous pemigatinib 13.5 mg
Number of subjects	9	7	9
Age categorical Units: Subjects			
Adults (18-64 years)	5	2	4
From 65-84 years	4	5	5
85 years and over	0	0	0

Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years			
arithmetic mean	61.8	63.4	66.9
standard deviation	± 10.89	± 11.43	± 8.80
Sex: Female, Male			
Units: participants			
Female	3	7	5
Male	6	0	4
Race/Ethnicity, Customized			
Units: Subjects			
White/Caucasian	9	7	9
Black/African-American	0	0	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Captured as Other	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	8	7	9
Unknown or Not Reported	0	0	0

Reporting group values	Part 3: Ref/continuous pemigatinib 20 mg	Total	
Number of subjects	2	201	
Age categorical			
Units: Subjects			
Adults (18-64 years)	1	127	
From 65-84 years	1	73	
85 years and over	0	1	
Age Continuous			
9999=The standard deviation was not calculated for a single participant.			
Units: years			
arithmetic mean	68.0		
standard deviation	± 7.07	-	
Sex: Female, Male			
Units: participants			
Female	1	113	
Male	1	88	
Race/Ethnicity, Customized			
Units: Subjects			
White/Caucasian	1	178	
Black/African-American	1	15	
Asian	0	4	
American-Indian/Alaska Native	0	0	
Native Hawaiian/Pacific Islander	0	0	
Captured as Other	0	4	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	15	

Not Hispanic or Latino	1	182	
Unknown or Not Reported	1	4	

End points

End points reporting groups

Reporting group title	Part 1: Intermittent pemigatinib 1/2/4 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 1/2/4 milligrams (mg) once daily (QD) on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.	
Reporting group title	Part 1: Intermittent pemigatinib 6 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 6 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.	
Reporting group title	Part 1: Intermittent pemigatinib 9 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.	
Reporting group title	Part 1: Intermittent pemigatinib 13.5 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.	
Reporting group title	Part 1: Intermittent pemigatinib 20 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 20 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.	
Reporting group title	Part 1: Continuous pemigatinib 9 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.	
Reporting group title	Part 1: Continuous pemigatinib 13.5 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.	
Reporting group title	Part 1: Continuous pemigatinib 20 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.	
Reporting group title	Part 1: Continuous pemigatinib 7.5 mg BID
Reporting group description:	
Participants self-administered oral pemigatinib 7.5 mg twice daily (BID) on Days 1 through 21 of each 21-day cycle.	
Reporting group title	Part 1: Continuous pemigatinib 10 mg BID
Reporting group description:	
Participants self-administered oral pemigatinib 10 mg BID on Days 1 through 21 of each 21-day cycle.	
Reporting group title	Part 2: Intermittent pemigatinib 9 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.	
Reporting group title	Part 2: Intermittent pemigatinib 13.5 mg QD
Reporting group description:	
Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.	
Reporting group title	Part 2: Continuous pemigatinib 9 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 2: Continuous pemigatinib 13.5 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 2: Continuous pemigatinib 20 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Gem/Cis/intermittent pemigatinib 9 mg

Reporting group description:

Participants received gemcitabine (Gem) intravenously starting at 1000 mg/meters squared (m^2) on Days 1 and 8 of each 21-day cycle. Cisplatin (Cis) was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin.

Reporting group title	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received gemcitabine intravenously starting at 1000 mg/m^2 on Days 1 and 8 of each 21-day cycle. Cisplatin was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin.

Reporting group title	Part 3: Tras/intermittent pemigatinib 13.5 mg

Reporting group description:

Trastuzumab (Tras) was administered as an open-label, commercial product at an initial intravenous dose of 8 mg/kilograms (kg), followed by 6 mg/kg intravenously once every 3 weeks. The dose could have been adjusted for toxicity management, per commercial labeling. The investigator could have interrupted, modified, or discontinued trastuzumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of trastuzumab.

Reporting group title	Part 3: Doc/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received docetaxel (Doc) intravenously starting at 75 mg/m^2 once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of docetaxel.

Reporting group title	Part 3: Pem/intermittent pemigatinib 9 mg

Reporting group description:

Participants received pembrolizumab (Pem) intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Pem/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor

approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Pem/continuous pemigatinib 13.5 mg

Reporting group description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Ref/continuous pemigatinib 9 mg

Reporting group description:

Retifanlimab (Ref) was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Ref/continuous pemigatinib 13.5 mg

Reporting group description:

Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Ref/continuous pemigatinib 20 mg

Reporting group description:

Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

Subject analysis set title	Parts 1 and 2: Intermittent pemigatinib 9 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Subject analysis set title	Parts 1 and 2: Intermittent pemigatinib 13.5 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Subject analysis set title	Parts 1 and 2: Continuous pemigatinib 9 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: Continuous pemigatinib 13.5 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: Continuous pemigatinib 20 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: intermittent or continuous pemigatinib
Subject analysis set type	Full analysis

Subject analysis set description:

Participant self-administered intermittent pemigatinib once daily (QD) or continuous pemigatinib QD or

twice daily (BID). Intermittent dosing: participants self-administered oral pemigatinib 1/2/4 milligrams (mg), 6 mg, 9 mg, 13.5 mg, or 20 mg once daily (QD) on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 9 mg, 13.5 mg, or 20 mg QD on Days 1 through 21 of each 21-day cycle in Part 1 or Part 2. Participants self-administered oral pemigatinib 7.5 mg or 10 mg BID on Days 1 through 21 of each 21-day cycle in Part 1.

Subject analysis set title	Part 1: Intermittent pemigatinib 1 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 1 milligram (mg) once daily (QD) on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Subject analysis set title	Part 1: Intermittent pemigatinib 2 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 2 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Subject analysis set title	Part 1: Intermittent pemigatinib 4 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered oral pemigatinib 4 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Subject analysis set title	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous oral pemigatinib 9 mg QD in either Part 1 or Part 2. Intermittent dosing: participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous oral pemigatinib 13.5 mg QD in either Part 1 or Part 2. Intermittent dosing: participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous oral pemigatinib 20 mg QD in either Part 1 or Part 2. Intermittent dosing: participants self-administered oral pemigatinib 20 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous oral pemigatinib 9 mg QD in either Part 1 or Part 2. Intermittent dosing: participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle in

either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous oral pemigatinib 13.5 mg QD in either Part 1 or Part 2. Intermittent dosing: participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous oral pemigatinib 20 mg QD in either Part 1 or Part 2. Intermittent dosing: participants self-administered oral pemigatinib 20 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Subject analysis set title	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous pemigatinib 13.5 mg QD in the fasted state in Part 2. Intermittent dosing: participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Subject analysis set title	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed
Subject analysis set type	Full analysis

Subject analysis set description:

Participants self-administered intermittent or continuous pemigatinib 13.5 mg QD in the fed state in Part 2. Intermittent dosing: participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. Continuous dosing: participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Subject analysis set title	Part 3: Pem/intermittent pemigatinib 13.5 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Primary: Parts 1 and 2 Combined: Number of participants with any treatment-emergent adverse event (TEAE)

End point title	Parts 1 and 2 Combined: Number of participants with any treatment-emergent adverse event (TEAE)[1][2]

End point description:

Adverse events were defined as the appearance of (or worsening of any pre-existing) undesirable sign(s), symptom(s), or medical condition(s) that occurred after a participant provided informed consent. Abnormal laboratory values or test results that occurred after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). TEAEs were defined as adverse events either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last dose of study drug.

End point type	Primary

End point timeframe:

up to 763 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: Statistical analysis was not conducted.

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

End point values	Part 1: Intermittent pemigatinib 1/2/4 mg QD	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 20 mg QD	Part 1: Continuous pemigatinib 7.5 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	6	4
Units: participants	3	3	6	4

End point values	Part 1: Continuous pemigatinib 10 mg BID	Parts 1 and 2: Intermittent pemigatinib 9 mg QD	Parts 1 and 2: Intermittent pemigatinib 13.5 mg QD	Parts 1 and 2: Continuous pemigatinib 9 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	7	50	14
Units: participants	3	7	50	14

End point values	Parts 1 and 2: Continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Continuous pemigatinib 20 mg QD		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	30	15		
Units: participants	30	15		

Statistical analyses

No statistical analyses for this end point

Primary: Part 3: Number of participants with any TEAE

End point title	Part 3: Number of participants with any TEAE[3][4]

End point description:

Adverse events were defined as the appearance of (or worsening of any pre-existing) undesirable sign(s), symptom(s), or medical condition(s) that occurred after a participant provided informed consent. Abnormal laboratory values or test results that occurred after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). TEAEs were defined as adverse events either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last dose of study drug.

End point type	Primary

End point timeframe:

up to 869 days

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not conducted.

[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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 9 mg	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	7	6	7
Units: participants	1	7	6	7

End point values	Part 3: Pem/intermittent pemigatinib 9 mg	Part 3: Pem/intermittent pemigatinib 13.5 mg	Part 3: Pem/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	14	9	7
Units: participants	3	14	9	7

End point values	Part 3: Ref/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 20 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	2		
Units: participants	9	2		

Statistical analyses

No statistical analyses for this end point

Primary: E0 following once daily dosing of pemigatinib as monotherapy in Parts 1 and 2

End point title	E0 following once daily dosing of pemigatinib as monotherapy in Parts 1 and 2[5]

End point description:

E0 was defined as the Baseline serum concentration of phosphate. The average serum concentration of phosphate on Cycle 1 Days 8 and 15 was chosen as a dependent variable for E-R analysis, which was independent of the intermittent dosing and continuous dosing regimens. Therefore, the intermittent dosing and continuous dosing groups from Parts 1 and 2 were combined into a single analysis group for E-R analysis.

End point type	Primary

End point timeframe:

predose on Days 1 and 14 of Cycle 1; anytime during visit on Day 1 of Cycle 2 and all subsequent cycles

Notes:

[5] - 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: Statistical analysis was not conducted.

End point values	Parts 1 and 2: intermittent or continuous pemigatinib			
Subject group type	Subject analysis set			
Number of subjects analysed	93			
Units: milligrams per deciliter (mg/dL)				
geometric mean (geometric coefficient of variation)	3.66 (± 1.91)			

Statistical analyses

No statistical analyses for this end point

Primary: EC50 following once daily dosing of pemigatinib as monotherapy in Parts 1 and 2

End point title	EC50 following once daily dosing of pemigatinib as monotherapy in Parts 1 and 2[6]

End point description:

EC50 was defined as the pemigatinib steady-state area under the plasma or serum concentration-time curve that increases 50% of serum phosphate. The average serum concentration of phosphate on Cycle 1 Days 8 and 15 was chosen as a dependent variable for E-R analysis, which was independent of the intermittent dosing and continuous dosing regimens. Therefore, the intermittent dosing and continuous dosing groups from Parts 1 and 2 were combined into a single analysis group for E-R analysis.

End point type	Primary

End point timeframe:

predose on Days 1 and 14 of Cycle 1; anytime during visit on Day 1 of Cycle 2 and all subsequent cycles

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: Statistical analysis was not conducted.

End point values	Parts 1 and 2: intermittent or continuous pemigatinib			
Subject group type	Subject analysis set			
Number of subjects analysed	93			
Units: hours*nanomoles				
geometric mean (geometric coefficient of variation)	1573 (± 21.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Emax following once daily dosing of pemigatinib as monotherapy in Parts 1 and 2

End point title	Emax following once daily dosing of pemigatinib as monotherapy in Parts 1 and 2[7]

End point description:

Emax was defined as the maximum degree of increasing of serum phosphate by pemigatinib. The average serum concentration of phosphate on Cycle 1 Days 8 and 15 was chosen as a dependent variable for E-R analysis, which was independent of the intermittent dosing and continuous dosing regimens. Therefore, the intermittent dosing and continuous dosing groups from Parts 1 and 2 were combined into a single analysis group for E-R analysis.

End point type	Primary

End point timeframe:

predose on Days 1 and 14 of Cycle 1; anytime during visit on Day 1 of Cycle 2 and all subsequent cycles

Notes:

[7] - 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: Statistical analysis was not conducted.

End point values	Parts 1 and 2: intermittent or continuous pemigatinib			
Subject group type	Subject analysis set			
Number of subjects analysed	93			
Units: mg/dL				
geometric mean (geometric coefficient of variation)	5.76 (± 7.76)			

Statistical analyses

No statistical analyses for this end point

Primary: Highest serum phosphate concentration following pemigatinib as monotherapy in Parts 1 and 2

End point title	Highest serum phosphate concentration following pemigatinib as monotherapy in Parts 1 and 2[8]

End point description:

Serum phosphate concentration was assessed throughout Parts 1 and 2. The average serum concentration of phosphate on Cycle 1 Days 8 and 15 was chosen as a dependent variable for E-R analysis, which was independent of the intermittent dosing and continuous dosing regimens. Therefore, the intermittent dosing and continuous dosing groups from Parts 1 and 2 were combined into a single analysis group for E-R analysis.

End point type	Primary

End point timeframe:

predose on Days 1 and 14 of Cycle 1; anytime during visit on Day 1 of Cycle 2 and all subsequent cycles

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: Statistical analysis was not conducted.

End point values	Parts 1 and 2: intermittent or continuous pemigatinib			
Subject group type	Subject analysis set			
Number of subjects analysed	93			
Units: mg/dL				
number (not applicable)				
Minimum value in range of highest values	3.5			
Maximum value in range of highest values	11.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Overall response rate (ORR)

End point title	Part 2: Overall response rate (ORR)[9]

End point description:

ORR was defined as the percentage of participants with a best overall response of complete response (CR) or partial response (PR), per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, as determined by the investigator. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 millimeters (mm). PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions.

End point type	Secondary

End point timeframe:

up to 126 days

Notes:

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

End point values	Part 2: Intermittent pemigatinib 9 mg QD	Part 2: Intermittent pemigatinib 13.5 mg QD	Part 2: Continuous pemigatinib 9 mg QD	Part 2: Continuous pemigatinib 13.5 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	44	5	20
Units: percentage of participants				
number (confidence interval 95%)	25.0 (0.6 to 80.6)	4.5 (0.6 to 15.5)	0.0 (0.0 to 52.2)	30.0 (11.9 to 54.3)

End point values	Part 2: Continuous pemigatinib 20 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of participants				

number (confidence interval 95%)	0.0 (0.0 to 45.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: ORR

End point title	Part 3: ORR[10]

End point description:

ORR was defined as the percentage of participants with a best overall response of CR or PR, per RECIST version 1.1, as determined by the investigator. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 millimeters (mm). PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions.

End point type	Secondary

End point timeframe:

up to 203 days

Notes:

[10] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 9 mg	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	7	6	7
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 97.5)	42.9 (9.9 to 81.6)	0.0 (0.0 to 45.9)	14.3 (0.4 to 57.9)

End point values	Part 3: Pem/intermittent pemigatinib 9 mg	Part 3: Pem/intermittent pemigatinib 13.5 mg	Part 3: Pem/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	14	9	7
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 70.8)	28.6 (8.4 to 58.1)	33.3 (7.5 to 70.1)	0.0 (0.0 to 41.0)

End point values	Part 3: Ref/continuous	Part 3: Ref/continuous		

	pemigatinib 13.5 mg	pemigatinib 20 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	2		
Units: percentage of participants				
number (confidence interval 95%)	22.2 (2.8 to 60.0)	0.0 (0.0 to 84.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Cmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1

End point title	Parts 1 and 2: Cmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1[11]

End point description:

Cmax was defined as the maximum observed plasma concentration. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose; 0.5, 1, 2, 4, 6, and 8 hours post-dose post-dose on Cycle 1 Day 1. Part 2: predose on Cycle 1 Day 1

Notes:

[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: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)	64.6 (± 9.16)	25.3 (± 9999)	13.6 (± 9999)	109 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	69	69	
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)	139 (± 79.8)	196 (± 121)	300 (± 135)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: tmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1

End point title	Parts 1 and 2: tmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1[12]

End point description:

tmax was defined as the time to the maximum observed plasma concentration. -9999 and 9999 denote that a range was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose; 0.5, 1, 2, 4, 6, and 8 hours post-dose post-dose on Cycle 1 Day 1. Part 2: predose on Cycle 1 Day 1

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: hours (hr)				
median (full range (min-max))	1.14 (1.00 to 2.08)	1 (-9999 to 9999)	5.92 (-9999 to 9999)	2.02 (-9999 to 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	69	69	
Units: hours (hr)				
median (full range (min-max))	1.17 (0.500 to 2.13)	1.20 (0.400 to 26.1)	1.98 (0.500 to 22.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: AUClast after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1

End point title	Parts 1 and 2: AUClast after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1[13]

End point description:

AUClast was defined as the area under the plasma or serum concentration-time curve from the time of

dosing to the last measurable concentration. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose; 0.5, 1, 2, 4, 6, and 8 hours post-dose post-dose on Cycle 1 Day 1. Part 2: predose on Cycle 1 Day 1

Notes:

[13] - 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: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: hr*ng/mL				
arithmetic mean (standard deviation)	641 (± 116)	190 (± 9999)	68.8 (± 9999)	1010 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	69	69	
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1140 (± 498)	1820 (± 1210)	2510 (± 935)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: AUC0-24 after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1

End point title	Parts 1 and 2: AUC0-24 after once daily dosing of pemigatinib as monotherapy on Cycle 1 Day 1[14]

End point description:

AUC0-24 was defined as the area under the plasma or serum concentration-time curve from time 0 to 24 hours post-dose. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose; 0.5, 1, 2, 4, 6, and 8 hours post-dose post-dose on Cycle 1 Day 1. Part 2: predose on Cycle 1 Day 1

Notes:

[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: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: hr*ng/mL				
arithmetic mean (standard deviation)	644 (± 115)	191 (± 9999)	9999 (± 9999)	1010 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	69	69	
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1150 (± 497)	1840 (± 1080)	2850 (± 1050)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Cmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: Cmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[15]

End point description:

Cmax was defined as the maximum observed plasma concentration. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14.
Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[15] - 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: Statistical analysis was not conducted for all treatment group comparisons

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: ng/mL				
arithmetic mean (standard deviation)	86.1 (± 38.0)	26.2 (± 9999)	22.9 (± 9999)	103 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: ng/mL				
arithmetic mean (standard deviation)	196 (± 123)	271 (± 151)	449 (± 172)	

Statistical analyses

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Part 1: Intermittent pemigatinib 6 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2841
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Part 1: Intermittent pemigatinib 6 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3042
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4315
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8214
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2595
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Part 1: Intermittent pemigatinib 6 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1259
Method	ANOVA

Secondary: Parts 1 and 2: tmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: tmax after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[16]

End point description:

tmax was defined as the time to the maximum observed plasma concentration. -9999 and 9999 denote that a range was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14.
Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[16] - 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: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: hr				
median (full range (min-max))	1.58 (0.983 to 23.7)	1.07 (-9999 to 9999)	3.98 (-9999 to 9999)	2.02 (-9999 to 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: hr				
median (full range (min-max))	1.00 (0.500 to 6.10)	1.13 (0.500 to 6.00)	1.12 (0.517 to 5.90)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: t1/2 after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: t1/2 after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[17]

End point description:

t1/2 was defined as the apparent plasma terminal phase disposition half-life. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14.
Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: hr				
arithmetic mean (standard deviation)	21.0 (± 22.8)	10.9 (± 9999)	18.1 (± 9999)	30.4 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: hr				
arithmetic mean (standard deviation)	17.2 (± 9.70)	17.4 (± 9.64)	13.1 (± 6.01)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Cmin after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: Cmin after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[18]

End point description:

Cmin was defined as the minimum observed plasma concentration over the dose interval. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14.
Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[18] - 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: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: ng/mL				
arithmetic mean (standard deviation)	30.0 (± 15.1)	3.24 (± 9999)	7.87 (± 9999)	23.9 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: ng/mL				
arithmetic mean (standard deviation)	49.9 (± 49.6)	71.7 (± 56.7)	104 (± 93.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: AUC0-24 after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: AUC0-24 after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[19]

End point description:

AUC0-24 was defined as the area under the plasma or serum concentration-time curve from time 0 to 24 hours post-dose. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14.
Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[19] - 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: Statistical analysis was not conducted for all treatment group comparisons

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1080 (± 301)	208 (± 9999)	322 (± 9999)	1380 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: hr*ng/mL				
arithmetic mean (standard deviation)	2180 (± 1630)	3010 (± 1890)	4350 (± 1480)	

Statistical analyses

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Part 1: Intermittent pemigatinib 6 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8577
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Part 1: Intermittent pemigatinib 6 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7238
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Part 1: Intermittent pemigatinib 6 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5923
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description: pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	

Comparison groups	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7634
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description:	
pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5749
Method	ANOVA

Statistical analysis title	ANOVA of log-transformed, dose-normalized data
Statistical analysis description:	
pairwise p-values from a 1-factor ANOVA of log-transformed, dose-normalized data (factor = dose)	
Comparison groups	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD v Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6877
Method	ANOVA

Secondary: Parts 1 and 2: CL/F after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: CL/F after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[20]
End point description:	
CL/F was defined as the apparent oral dose clearance. 9999 denotes that a standard deviation was not calculated for a single participant.	
End point type	Secondary
End point timeframe:	
Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14. Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14	

Notes:

[20] - 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: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: Liters per hr (L/hr)				
arithmetic mean (standard deviation)	12.0 (± 3.14)	9.86 (± 9999)	12.8 (± 9999)	5.93 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: Liters per hr (L/hr)				
arithmetic mean (standard deviation)	15.7 (± 17.7)	11.9 (± 5.72)	10.3 (± 3.01)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Vz/F after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: Vz/F after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[21]

End point description:

Vz/F was defined as the apparent volume of distribution. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14.
Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[21] - 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: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: Liters				

arithmetic mean (standard deviation)	301 (± 241)	156 (± 9999)	334 (± 9999)	260 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: Liters				
arithmetic mean (standard deviation)	246 (± 76.1)	274 (± 165)	180 (± 49.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Accumulation ratio after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)

End point title	Parts 1 and 2: Accumulation ratio after once daily dosing of pemigatinib as monotherapy on Cycle 1 Days 8 and 14 (steady state)[22]

End point description:

The accumulation ratio was defined as the ratio of the accumulation of a drug under steady-state conditions as compared to a single dose. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

Part 1: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14.
Part 2: predose on Cycle 1 Days 8 and 14; 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted.

End point values	Part 1: Intermittent pemigatinib 6 mg QD	Part 1: Intermittent pemigatinib 1 mg QD	Part 1: Intermittent pemigatinib 2 mg QD	Part 1: Intermittent pemigatinib 4 mg QD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	1	1
Units: ratio				
arithmetic mean (standard deviation)	1.67 (± 0.264)	1.09 (± 9999)	1.64 (± 9999)	1.36 (± 9999)

End point values	Parts 1 and 2: Intermittent/continuous pemigatinib 9 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Intermittent/continuous pemigatinib 20 mg QD	

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	57	13	
Units: ratio				
arithmetic mean (standard deviation)	1.71 (± 0.534)	1.69 (± 0.538)	1.76 (± 0.476)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Cmax steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point title	Parts 1 and 2: Cmax steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point description:

Cmax was defined as the maximum observed plasma concentration.

End point type	Secondary

End point timeframe:

Cycles 1 and 2: predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Day 14

End point values	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: ng/mL				
arithmetic mean (standard deviation)	215 (± 86.5)	179 (± 82.8)		

Statistical analyses

Statistical analysis title	crossover ANOVA of log-transformed data
Comparison groups	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted v Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.143
Method	ANOVA

Secondary: Parts 1 and 2: tmax steady state following administration of pemigatinib

in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states	
End point title	Parts 1 and 2: tmax steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point description:

tmax was defined as the time to the maximum observed plasma concentration.

End point type	Secondary

End point timeframe:

Cycles 1 and 2: predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Day 14

End point values	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: hr				
median (full range (min-max))	1.58 (0.500 to 5.78)	4.02 (1.00 to 7.58)		

Statistical analyses

Statistical analysis title	crossover ANOVA of log-transformed data
Comparison groups	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted v Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0013
Method	ANOVA

Secondary: Parts 1 and 2: t1/2 steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states	
End point title	Parts 1 and 2: t1/2 steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point description:

t1/2 was defined as the apparent plasma terminal phase disposition half-life.

End point type	Secondary

End point timeframe:

Cycles 1 and 2: predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Day 14

End point values	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: hr				
arithmetic mean (standard deviation)	19.2 (± 10.5)	23.8 (± 17.5)		

Statistical analyses

Statistical analysis title	crossover ANOVA of log-transformed data
Comparison groups	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted v Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.319
Method	ANOVA

Secondary: Parts 1 and 2: Cmin steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point title	Parts 1 and 2: Cmin steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point description:

Cmin was defined as the minimum observed plasma concentration over the dose interval.

End point type	Secondary

End point timeframe:

Cycles 1 and 2: predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Day 14

End point values	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: ng/mL				
arithmetic mean (standard deviation)	61.1 (± 33.5)	65.7 (± 34.7)		

Statistical analyses

Statistical analysis title	crossover ANOVA of log-transformed data
Comparison groups	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted v Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.128
Method	ANOVA

Secondary: Parts 1 and 2: AUC0-24 steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point title	Parts 1 and 2: AUC0-24 steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point description:

AUC0-24 was defined as the area under the plasma or serum concentration-time curve from time 0 to 24 hours post-dose.

End point type	Secondary

End point timeframe:

Cycles 1 and 2: predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Day 14

End point values	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: hr*ng/mL				
arithmetic mean (standard deviation)	2580 (± 999)	2910 (± 1310)		

Statistical analyses

Statistical analysis title	crossover ANOVA of log-transformed data
Comparison groups	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted v Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed

Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.305
Method	ANOVA

Secondary: Parts 1 and 2: CL/F steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point title	Parts 1 and 2: CL/F steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point description:

CL/F was defined as the apparent oral dose clearance.

End point type	Secondary

End point timeframe:

Cycles 1 and 2: predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Day 14

End point values	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: L/hr				
arithmetic mean (standard deviation)	12.4 (± 4.94)	11.3 (± 4.87)		

Statistical analyses

Statistical analysis title	crossover ANOVA of log-transformed data
Comparison groups	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted v Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.305
Method	ANOVA

Secondary: Parts 1 and 2: Vz/F steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point title	Parts 1 and 2: Vz/F steady state following administration of pemigatinib in the fasted (Cycle 1 Day 14) and fed (Cycle 2 Day 14) states

End point description:

Vz/F was defined as the apparent volume of distribution.

End point type	Secondary

End point timeframe:

Cycles 1 and 2: predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Day 14

End point values	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: Liters				
arithmetic mean (standard deviation)	307 (± 139)	364 (± 262)		

Statistical analyses

Statistical analysis title	crossover ANOVA of log-transformed data
Comparison groups	Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fasted v Part 2: intermittent/continuous pemigatinib 13.5 mg QD, fed
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.772
Method	ANOVA

Secondary: Part 3: Cmax of pemigatinib as part of combination therapy on Cycle 1 Day 1

End point title	Part 3: Cmax of pemigatinib as part of combination therapy on Cycle 1 Day 1[23]

End point description:

Cmax was defined as the maximum observed plasma concentration.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 1

Notes:

[23] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	7	3
Units: ng/mL				
arithmetic mean (standard deviation)	234 (± 84.1)	259 (± 55.4)	214 (± 98.2)	137 (± 65.7)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: ng/mL				
arithmetic mean (standard deviation)	199 (± 99.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: tmax of pemigatinib as part of combination therapy on Cycle 1 Day 1

End point title	Part 3: tmax of pemigatinib as part of combination therapy on Cycle 1 Day 1[24]

End point description:

tmax was defined as the time to the maximum observed plasma concentration.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 1

Notes:

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

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	7	3
Units: hr				
median (full range (min-max))	2.00 (0.500 to 22.6)	0.783 (0.500 to 18.6)	1.00 (0.500 to 3.98)	1.98 (1.00 to 4.00)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: hr				
median (full range (min-max))	1.05 (0.500 to 23.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: AUClast of pemigatinib as part of combination therapy on Cycle 1 Day 1

End point title	Part 3: AUClast of pemigatinib as part of combination therapy on Cycle 1 Day 1[25]

End point description:

AUClast was defined as the area under the plasma or serum concentration-time curve from the time of dosing to the last measurable concentration.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 1

Notes:

[25] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	7	3
Units: hr*ng/mL				
arithmetic mean (standard deviation)	2890 (± 1010)	2040 (± 513)	1890 (± 491)	1480 (± 587)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1880 (± 821)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: AUC0-24 of pemigatinib as part of combination therapy on Cycle 1 Day 1

End point title	Part 3: AUC0-24 of pemigatinib as part of combination therapy on Cycle 1 Day 1[26]

End point description:

AUC0-24 was defined as the area under the plasma or serum concentration-time curve from time 0 to 24 hours post-dose.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 1

Notes:

[26] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	7	3
Units: hr*ng/mL				
arithmetic mean (standard deviation)	2920 (± 1070)	1890 (± 269)	1890 (± 471)	1550 (± 552)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1910 (± 838)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Cmax of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: Cmax of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[27]

End point description:

Cmax was defined as the maximum observed plasma concentration.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: ng/mL				
arithmetic mean (standard deviation)	214 (± 203)	404 (± 41.7)	231 (± 99.4)	166 (± 52.1)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ng/mL				
arithmetic mean (standard deviation)	255 (± 119)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: tmax of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: tmax of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[28]

End point description:

tmax was defined as the time to the maximum observed plasma concentration.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[28] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: hr				
median (full range (min-max))	1.50 (0.950 to 4.00)	0.583 (0.500 to 1.07)	1.90 (0.500 to 2.08)	5.78 (1.25 to 6.08)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: hr				
median (full range (min-max))	1.08 (0.500 to 7.98)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: t1/2 of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: t1/2 of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[29]

End point description:

t1/2 was defined as the apparent plasma terminal phase disposition half-life. 9999 denotes that a standard deviation was not calculated for a single participant.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[29] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: hr				
arithmetic mean (standard deviation)	10.6 (± 3.29)	15.3 (± 2.64)	14.7 (± 6.43)	15.3 (± 0.207)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: hr				
arithmetic mean (standard deviation)	17.0 (± 6.90)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Cmin of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: Cmin of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[30]

End point description:

Cmin was defined as the minimum observed plasma concentration over the dose interval.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[30] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: ng/mL				
arithmetic mean (standard deviation)	48.5 (± 57.8)	64.2 (± 25.8)	63.1 (± 32.4)	58.0 (± 31.6)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ng/mL				
arithmetic mean (standard deviation)	56.6 (± 31.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: AUC0-24 of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: AUC0-24 of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[31]

End point description:

AUC0-24 was defined as the area under the plasma or serum concentration-time curve from time 0 to 24 hours post-dose.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[31] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1650 (± 1060)	3440 (± 672)	2910 (± 1390)	2400 (± 628)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: hr*ng/mL				
arithmetic mean (standard deviation)	2400 (± 967)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: CL/F of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: CL/F of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[32]

End point description:

CL/F was defined as the apparent oral dose clearance.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[32] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: L/hr				
arithmetic mean (standard deviation)	24.5 (± 17.7)	8.26 (± 1.39)	12.7 (± 9.03)	8.03 (± 1.89)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: L/hr				
arithmetic mean (standard deviation)	13.4 (± 5.46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Vz/F of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: Vz/F of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[33]

End point description:

Vz/F was defined as the apparent volume of distribution.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: Liters				
arithmetic mean (standard deviation)	376 (± 261)	182 (± 43.2)	227 (± 82.2)	177 (± 39.8)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: Liters				
arithmetic mean (standard deviation)	303 (± 136)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Accumulation ratio of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)

End point title	Part 3: Accumulation ratio of pemigatinib as part of combination therapy on Cycle 1 Day 14 (steady state)[34]

End point description:

The accumulation ratio was defined as the ratio of the accumulation of a drug under steady-state conditions as compared to a single dose.

End point type	Secondary

End point timeframe:

predose and 0.5, 1, 2, 4, 6, and 8 hours post-dose on Cycle 1 Day 14

Notes:

[34] - 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: Statistical analysis was not conducted.

End point values	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: ratio				
arithmetic mean (standard deviation)	0.604 (± 0.265)	1.90 (± 0.432)	1.52 (± 0.772)	1.65 (± 0.501)

End point values	Part 3: Pem/intermittent pemigatinib 13.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ratio				
arithmetic mean (standard deviation)	1.53 (± 0.381)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

up to 869 days

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs), defined as adverse events either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last dose of study drug, are reported for all enrolled participants who received at least 1 dose of study drug (Safety Population).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

Reporting groups

Reporting group title	Part 1: Intermittent pemigatinib 1/2/4 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 1/2/4 milligrams (mg) once daily (QD) on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 1: Intermittent pemigatinib 6 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 6 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Parts 1 and 2: Intermittent pemigatinib 9 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Parts 1 and 2: Intermittent pemigatinib 13.5 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in either Part 1 or Part 2. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Part 1: Intermittent pemigatinib 20 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 20 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule in Part 1. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break.

Reporting group title	Parts 1 and 2: Continuous pemigatinib 9 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Reporting group title	Parts 1 and 2: Continuous pemigatinib 13.5 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Reporting group title	Parts 1 and 2: Continuous pemigatinib 20 mg QD

Reporting group description:

Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle in either Part 1 or Part 2.

Reporting group title	Part 1: Continuous pemigatinib 7.5 mg BID

Reporting group description:

Participants self-administered oral pemigatinib 7.5 mg twice daily (BID) on Days 1 through 21 of each

21-day cycle.

Reporting group title	Part 1: Continuous pemigatinib 10 mg BID

Reporting group description:

Participants self-administered oral pemigatinib 10 mg BID on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Gem/Cis/intermittent pemigatinib 9 mg

Reporting group description:

Participants received gemcitabine (Gem) intravenously starting at 1000 mg/meters squared (m^2) on Days 1 and 8 of each 21-day cycle. Cisplatin (Cis) was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin

Reporting group title	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received gemcitabine intravenously starting at 1000 mg/m^2 on Days 1 and 8 of each 21-day cycle. Cisplatin was administered intravenously starting at 70 mg/m^2 once every 3 weeks on Day 1 of each 21-day cycle. Both gemcitabine and cisplatin doses could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of gemcitabine/cisplatin.

Reporting group title	Part 3: Tras/intermittent pemigatinib 13.5 mg

Reporting group description:

Trastuzumab (Tras) was administered as an open-label, commercial product at an initial intravenous dose of 8 mg/kilograms (kg), followed by 6 mg/kg intravenously once every 3 weeks. The dose could have been adjusted for toxicity management, per commercial labeling. The investigator could have interrupted, modified, or discontinued trastuzumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of trastuzumab.

Reporting group title	Part 3: Doc/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received docetaxel (Doc) intravenously starting at 75 mg/m^2 once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued chemotherapy with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of docetaxel.

Reporting group title	Part 3: Pem/intermittent pemigatinib 9 mg

Reporting group description:

Participants received pembrolizumab (Pem) intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 9 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Pem/intermittent pemigatinib 13.5 mg

Reporting group description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on a 2-weeks-on therapy and 1-week-off therapy schedule. The treatment cycle consisted of: Days 1 through 14: pemigatinib QD; Days 15 through 21: treatment break. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Pem/continuous pemigatinib 13.5 mg

Reporting group description:

Participants received pembrolizumab intravenously at 200 mg once every 3 weeks on Day 1 of each cycle. The dose could have been adjusted for toxicity management per commercial labeling. The investigator could have interrupted, modified, or discontinued pembrolizumab with medical monitor approval. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle. It was permissible to continue pemigatinib administration during the toxicity break of pembrolizumab.

Reporting group title	Part 3: Ref/continuous pemigatinib 9 mg

Reporting group description:

Retifanlimab (Ref) was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 9 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Ref/continuous pemigatinib 13.5 mg

Reporting group description:

Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 13.5 mg QD on Days 1 through 21 of each 21-day cycle.

Reporting group title	Part 3: Ref/continuous pemigatinib 20 mg

Reporting group description:

Retifanlimab was administered once every 4 weeks on a 28-day cycle as an open-label product, at an initial intravenous dose of 500 mg. Participants self-administered oral pemigatinib 20 mg QD on Days 1 through 21 of each 21-day cycle.

Serious adverse events	Part 1: Intermittent pemigatinib 1/2/4 mg QD	Part 1: Intermittent pemigatinib 6 mg QD	Parts 1 and 2: Intermittent pemigatinib 9 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	3 / 7 (42.86%)
number of deaths (all causes)	3	2	6
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypothermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood osmolarity decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral osteophyte			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
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	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Parts 1 and 2: Intermittent pemigatinib 13.5 mg QD	Part 1: Intermittent pemigatinib 20 mg QD	Parts 1 and 2: Continuous pemigatinib 9 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 50 (42.00%)	3 / 6 (50.00%)	6 / 14 (42.86%)
number of deaths (all causes)	37	6	10
number of deaths resulting from adverse events	4	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			

subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Metastases to spine			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Metastatic neoplasm			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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

Facial pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Dyspnoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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 aspiration			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	0 / 14 (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
Respiratory failure			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device occlusion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 osmolarity decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 test positive			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Alcohol poisoning			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Atrial flutter			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 tamponade			

subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Hydrocephalus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Syncope			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Febrile neutropenia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Vomiting			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Erythema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hydronephrosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Hypothyroidism			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Flank pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Vertebral osteophyte			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (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
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 sinusitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	2 / 50 (4.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	Parts 1 and 2: Continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Continuous pemigatinib 20 mg QD	Part 1: Continuous pemigatinib 7.5 mg BID
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 30 (46.67%)	7 / 15 (46.67%)	2 / 4 (50.00%)
number of deaths (all causes)	21	10	4
number of deaths resulting from adverse events	2	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Facial pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	3 / 30 (10.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 3	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (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
Oedema peripheral			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dyspnoea			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood osmolarity decreased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Clostridium test positive			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial flutter			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral osteophyte			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			

subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			

subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (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
Pharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	2 / 4 (50.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (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
Metabolic alkalosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: Continuous pemigatinib 10 mg BID	Part 3: Gem/Cis/intermittent pemigatinib 9 mg	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 1 (100.00%)	3 / 7 (42.86%)
number of deaths (all causes)	2	1	7
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood osmolarity decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral osteophyte			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	6 / 7 (85.71%)	1 / 3 (33.33%)
number of deaths (all causes)	5	5	3
number of deaths resulting from	0	1	1

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	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
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (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
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	1 / 7 (14.29%)	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
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Completed suicide			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (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
Mental status changes			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 osmolarity decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Alcohol poisoning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 flutter			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	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
Myoclonus			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	1 / 7 (14.29%)	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
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	1 / 7 (14.29%)	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
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral osteophyte			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	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 / 1	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	2 / 7 (28.57%)	0 / 3 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
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	Part 3: Pem/intermittent pemigatinib 13.5 mg	Part 3: Pem/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 9 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 14 (50.00%)	3 / 9 (33.33%)	4 / 7 (57.14%)
number of deaths (all causes)	9	6	6
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary			

disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood osmolarity decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium test positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fall			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dysarthria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (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
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral osteophyte			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chronic sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 3: Ref/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 20 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 9 (55.56%)	2 / 2 (100.00%)	
number of deaths (all causes)	3	0	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Facial pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			

subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device occlusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood osmolarity decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium test positive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Depressed level of consciousness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	2 / 2 (100.00%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral osteophyte			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic alkalosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 1: Intermittent pemigatinib 1/2/4 mg QD	Part 1: Intermittent pemigatinib 6 mg QD	Parts 1 and 2: Intermittent pemigatinib 9 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 4 (75.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyogenic granuloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	4 / 7 (57.14%)
occurrences (all)	1	1	4
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast fibrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Nasal septum deviation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pulmonary embolism			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Adjustment disorder with depressed mood			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Blood 1,25-dihydroxycholecalciferol decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood 1,25-dihydroxycholecalciferol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood 25-hydroxycholecalciferol decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	3
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood folate decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Weight decreased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail avulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nodal rhythm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Somnolence			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract cortical			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chorioretinopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry age-related macular degeneration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Entropion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Keratopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal degeneration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal fovea disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scleral discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scleral hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ulcerative keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Visual acuity reduced			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreoretinal traction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chapped lips			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	3
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	3 / 7 (42.86%)
occurrences (all)	0	1	5
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Lip ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Oesophageal hypomotility			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Tongue erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tooth disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail bed bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nail hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	4
Paraneoplastic pemphigus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Skin irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Autoimmune nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoparathyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Trismus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Body tinea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Catheter site cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Herpes ophthalmic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Dehydration			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Fluid overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	4 / 7 (57.14%)
occurrences (all)	0	2	13
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyponatraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	4
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Non-serious adverse events	Parts 1 and 2: Intermittent pemigatinib 13.5 mg QD	Part 1: Intermittent pemigatinib 20 mg QD	Parts 1 and 2: Continuous pemigatinib 9 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 50 (100.00%)	6 / 6 (100.00%)	14 / 14 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pyogenic granuloma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Seborrhoeic keratosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Skin papilloma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	5	0	0
Systolic hypertension			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Venous thrombosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Catheter site pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	18 / 50 (36.00%)	2 / 6 (33.33%)	8 / 14 (57.14%)
occurrences (all)	21	2	8
Gait disturbance			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Pyrexia			

subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	3
Swelling face			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypersensitivity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Breast fibrosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	6 / 50 (12.00%)	2 / 6 (33.33%)	2 / 14 (14.29%)
occurrences (all)	6	2	2
Dysphonia			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			

subjects affected / exposed	2 / 50 (4.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Dyspnoea exertional			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	6 / 50 (12.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	7	1	2
Haemoptysis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Nasal discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nasal septum deviation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	9	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pharyngeal inflammation			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Pneumonitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Respiratory tract congestion			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Rhinorrhoea			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sneezing			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	1	2	1
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	4 / 50 (8.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	4	0	1
Confusional state			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Disorientation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			

subjects affected / exposed	4 / 50 (8.00%)	0 / 6 (0.00%)	5 / 14 (35.71%)
occurrences (all)	6	0	5
Amylase increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 50 (14.00%)	0 / 6 (0.00%)	5 / 14 (35.71%)
occurrences (all)	8	0	5
Blood 1,25-dihydroxycholecalciferol decreased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Blood 1,25-dihydroxycholecalciferol increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood 25-hydroxycholecalciferol decreased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	3 / 14 (21.43%)
occurrences (all)	7	0	3
Blood bilirubin increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Blood folate decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood glucose increased			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram abnormal			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin D increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	5 / 50 (10.00%)	2 / 6 (33.33%)	3 / 14 (21.43%)
occurrences (all)	5	2	3
Weight increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	4
White blood cell count decreased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
White blood cell count increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	3 / 50 (6.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	3	0	3
Infusion related reaction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Limb injury			

subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Lip injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail avulsion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Skin abrasion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Tooth fracture			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Wound complication			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Nodal rhythm			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palpitations			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Dysarthria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	5 / 50 (10.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	5	1	2
Headache			
subjects affected / exposed	2 / 50 (4.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Hyperaesthesia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Neuropathy peripheral			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1

Paraesthesia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	4 / 50 (8.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	4	1	2
Tremor			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 50 (20.00%)	2 / 6 (33.33%)	6 / 14 (42.86%)
occurrences (all)	14	2	8
Iron deficiency anaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Leukopenia			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	4 / 50 (8.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	6	0	1
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Tinnitus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blepharospasm			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cataract cortical			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chorioretinopathy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Corneal epithelium defect			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Detachment of macular retinal pigment epithelium			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry age-related macular degeneration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	8 / 50 (16.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	9	1	2
Entropion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	2 / 50 (4.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	3	1	0
Eye pruritus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Eyelid ptosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Growth of eyelashes			
subjects affected / exposed	6 / 50 (12.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	6	0	0
Iridocyclitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Keratopathy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lacrimation decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Macular fibrosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Ocular discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Ocular hypertension			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Periorbital oedema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Photophobia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Punctate keratitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Retinal degeneration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Retinal disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Retinal fovea disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Retinal oedema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Scleral discolouration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Scleral hyperaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Subretinal fluid			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Ulcerative keratitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	4 / 50 (8.00%)	2 / 6 (33.33%)	0 / 14 (0.00%)
occurrences (all)	4	2	0
Visual acuity reduced			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Visual impairment			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreoretinal traction syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	4 / 50 (8.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	4	0	1
Abdominal pain			

subjects affected / exposed	10 / 50 (20.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	10	1	2
Abdominal pain lower			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Abdominal tenderness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	4 / 50 (8.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	4	1	0
Chapped lips			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	14 / 50 (28.00%)	2 / 6 (33.33%)	4 / 14 (28.57%)
occurrences (all)	14	2	4
Diarrhoea			
subjects affected / exposed	12 / 50 (24.00%)	2 / 6 (33.33%)	3 / 14 (21.43%)
occurrences (all)	12	2	3
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	17 / 50 (34.00%)	2 / 6 (33.33%)	5 / 14 (35.71%)
occurrences (all)	19	2	5
Dyspepsia			

subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Dysphagia			
subjects affected / exposed	1 / 50 (2.00%)	2 / 6 (33.33%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Eructation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Gingival pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Hiatus hernia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			

subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Loose tooth			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	8 / 50 (16.00%)	2 / 6 (33.33%)	6 / 14 (42.86%)
occurrences (all)	8	2	6
Oesophageal hypomotility			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oesophageal ulcer			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	3 / 50 (6.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	4	0	1
Paraesthesia oral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rectal tenesmus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	11 / 50 (22.00%)	3 / 6 (50.00%)	6 / 14 (42.86%)
occurrences (all)	13	3	8
Tongue erythema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	7 / 50 (14.00%)	1 / 6 (16.67%)	4 / 14 (28.57%)
occurrences (all)	7	1	4
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Portal vein thrombosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	15 / 50 (30.00%)	1 / 6 (16.67%)	6 / 14 (42.86%)
occurrences (all)	15	1	7
Decubitus ulcer			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	5	0	0
Ecchymosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypertrichosis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail bed bleeding			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			

subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	5	0	2
Nail hypertrophy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nail ridging			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Onycholysis			
subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	5	0	2
Onychomadesis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Pain of skin			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Paraneoplastic pemphigus			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	2	0

Rash maculo-papular			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Skin fissures			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Autoimmune nephritis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lower urinary tract symptoms			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	2
Urinary tract obstruction			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoparathyroidism			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 50 (8.00%)	2 / 6 (33.33%)	4 / 14 (28.57%)
occurrences (all)	4	2	5
Arthritis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	3 / 50 (6.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	3	0	2
Bone pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Joint swelling			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	5	0	0
Neck pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Osteoarthritis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	3 / 50 (6.00%)	1 / 6 (16.67%)	3 / 14 (21.43%)
occurrences (all)	3	1	3
Trismus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Body tinea			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Catheter site cellulitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	4	0	2
Conjunctivitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	2 / 50 (4.00%)	2 / 6 (33.33%)	2 / 14 (14.29%)
occurrences (all)	2	2	4
Pharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Skin infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tinea versicolour			
subjects affected / exposed	0 / 50 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	3
Urinary tract infection bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			

subjects affected / exposed	12 / 50 (24.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	12	1	1
Dehydration			
subjects affected / exposed	6 / 50 (12.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	7	2	1
Fluid overload			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	5 / 50 (10.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	8	0	2
Hypercholesterolaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 50 (4.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Hyperphosphataemia			
subjects affected / exposed	39 / 50 (78.00%)	4 / 6 (66.67%)	8 / 14 (57.14%)
occurrences (all)	78	6	12
Hypertriglyceridaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			

subjects affected / exposed	3 / 50 (6.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	4	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	3 / 50 (6.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	3	0	2
Hypomagnesaemia			
subjects affected / exposed	2 / 50 (4.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	3	1	2
Hyponatraemia			
subjects affected / exposed	3 / 50 (6.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	5	1	0
Hypophosphataemia			
subjects affected / exposed	10 / 50 (20.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	17	1	0
Malnutrition			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	3 / 50 (6.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	3	1	0

Non-serious adverse events	Parts 1 and 2: Continuous pemigatinib 13.5 mg QD	Parts 1 and 2: Continuous pemigatinib 20 mg QD	Part 1: Continuous pemigatinib 7.5 mg BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 30 (100.00%)	15 / 15 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Melanocytic naevus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyogenic granuloma			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Hypotension			
subjects affected / exposed	6 / 30 (20.00%)	1 / 15 (6.67%)	1 / 4 (25.00%)
occurrences (all)	6	1	1
Systolic hypertension			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Venous thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Fatigue			
subjects affected / exposed	8 / 30 (26.67%)	4 / 15 (26.67%)	2 / 4 (50.00%)
occurrences (all)	8	5	3
Gait disturbance			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	4 / 30 (13.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	4	3	0
Pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Performance status decreased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
Swelling face			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tenderness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Reproductive system and breast disorders			
Breast fibrosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	6 / 30 (20.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
Dysphonia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Dyspnoea			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	4 / 30 (13.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	4	2	0
Haemoptysis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Nasal congestion			

subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Nasal discomfort			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nasal dryness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	4 / 30 (13.33%)	3 / 15 (20.00%)	0 / 4 (0.00%)
occurrences (all)	6	3	0
Paranasal sinus discomfort			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Pulmonary embolism			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rales			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Sinus pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Wheezing			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	4 / 30 (13.33%)	1 / 15 (6.67%)	1 / 4 (25.00%)
occurrences (all)	4	1	1
Confusional state			

subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Depression			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Disorientation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Alanine aminotransferase increased			
subjects affected / exposed	7 / 30 (23.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	11	2	0
Amylase increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 30 (23.33%)	3 / 15 (20.00%)	0 / 4 (0.00%)
occurrences (all)	10	4	0
Blood 1,25-dihydroxycholecalciferol decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood 1,25-dihydroxycholecalciferol increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood 25-hydroxycholecalciferol decreased			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	11 / 30 (36.67%)	4 / 15 (26.67%)	1 / 4 (25.00%)
occurrences (all)	18	4	4
Blood folate decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram abnormal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	3 / 30 (10.00%)	5 / 15 (33.33%)	3 / 4 (75.00%)
occurrences (all)	3	7	3
Weight increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			

subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
White blood cell count increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	5 / 30 (16.67%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	8	0	1
Infusion related reaction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nail avulsion			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Procedural pain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Skin abrasion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wound complication			

subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Tachycardia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	4 / 30 (13.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	6	1	0
Dysarthria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	9 / 30 (30.00%)	4 / 15 (26.67%)	4 / 4 (100.00%)
occurrences (all)	9	5	4
Headache			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hyperaesthesia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Memory impairment			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Paraesthesia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			

subjects affected / exposed	2 / 30 (6.67%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Tremor			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 30 (20.00%)	4 / 15 (26.67%)	2 / 4 (50.00%)
occurrences (all)	9	5	3
Iron deficiency anaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Leukopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Microcytic anaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0

Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Deafness			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ear congestion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blepharospasm			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cataract			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cataract cortical			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Cataract nuclear			

subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Chorioretinopathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dry age-related macular degeneration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	10 / 30 (33.33%)	4 / 15 (26.67%)	1 / 4 (25.00%)
occurrences (all)	11	4	1
Entropion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye discharge			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye irritation			

subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Eye pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eyelid function disorder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eyelid pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Iridocyclitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Keratitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Keratopathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Macular fibrosis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Ocular discomfort			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	3 / 30 (10.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Ocular hypertension			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Periorbital oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Photopsia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Retinal degeneration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal fovea disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scleral discolouration			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Scleral hyperaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	6 / 30 (20.00%)	1 / 15 (6.67%)	2 / 4 (50.00%)
occurrences (all)	6	1	2
Ulcerative keratitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Vision blurred			
subjects affected / exposed	5 / 30 (16.67%)	3 / 15 (20.00%)	0 / 4 (0.00%)
occurrences (all)	5	5	0
Visual acuity reduced			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Visual impairment			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreoretinal traction syndrome			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Vitreous floaters			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 30 (6.67%)	3 / 15 (20.00%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Abdominal pain			
subjects affected / exposed	6 / 30 (20.00%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	6	2	0
Abdominal pain lower			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 30 (0.00%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Chapped lips			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Colitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	12 / 30 (40.00%)	4 / 15 (26.67%)	1 / 4 (25.00%)
occurrences (all)	13	6	2
Diarrhoea			
subjects affected / exposed	15 / 30 (50.00%)	9 / 15 (60.00%)	1 / 4 (25.00%)
occurrences (all)	18	12	2
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	13 / 30 (43.33%)	8 / 15 (53.33%)	2 / 4 (50.00%)
occurrences (all)	13	8	2
Dyspepsia			
subjects affected / exposed	5 / 30 (16.67%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	5	0	1
Dysphagia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Eructation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 30 (3.33%)	3 / 15 (20.00%)	1 / 4 (25.00%)
occurrences (all)	1	3	1
Gingival pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Glossodynia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Loose tooth			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	13 / 30 (43.33%)	5 / 15 (33.33%)	3 / 4 (75.00%)
occurrences (all)	15	5	3
Oesophageal hypomotility			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Oesophageal stenosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal ulcer			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed	7 / 30 (23.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	8	2	0
Paraesthesia oral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	15 / 30 (50.00%)	7 / 15 (46.67%)	2 / 4 (50.00%)
occurrences (all)	18	11	2
Tongue erythema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	9 / 30 (30.00%)	3 / 15 (20.00%)	2 / 4 (50.00%)
occurrences (all)	12	6	4
Hepatobiliary disorders			
Hyperbilirubinaemia			

subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	11 / 30 (36.67%)	5 / 15 (33.33%)	1 / 4 (25.00%)
occurrences (all)	12	5	1
Decubitus ulcer			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	7 / 30 (23.33%)	1 / 15 (6.67%)	1 / 4 (25.00%)
occurrences (all)	7	1	1
Ecchymosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0

Hypertrichosis			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Lichenoid keratosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail bed bleeding			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nail bed tenderness			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nail discolouration			
subjects affected / exposed	7 / 30 (23.33%)	3 / 15 (20.00%)	1 / 4 (25.00%)
occurrences (all)	7	3	1
Nail hypertrophy			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nail ridging			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Onychoclasis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Onycholysis			
subjects affected / exposed	9 / 30 (30.00%)	3 / 15 (20.00%)	1 / 4 (25.00%)
occurrences (all)	11	3	1
Onychomadesis			
subjects affected / exposed	6 / 30 (20.00%)	0 / 15 (0.00%)	2 / 4 (50.00%)
occurrences (all)	7	0	3
Pain of skin			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	8 / 30 (26.67%)	3 / 15 (20.00%)	2 / 4 (50.00%)
occurrences (all)	9	5	2
Paraneoplastic pemphigus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Psoriasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	5 / 30 (16.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	8	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rash papular			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin induration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin lesion			

subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 30 (10.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Autoimmune nephritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bladder spasm			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Haematuria			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lower urinary tract symptoms			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Micturition urgency			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Urinary tract obstruction			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urinary tract pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoparathyroidism			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 30 (13.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	6	1	0
Arthritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	3 / 30 (10.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	4	0	1
Bone pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	2 / 30 (6.67%)	2 / 15 (13.33%)	1 / 4 (25.00%)
occurrences (all)	2	2	1
Joint swelling			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			

subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	5 / 30 (16.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Neck pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	5 / 30 (16.67%)	3 / 15 (20.00%)	0 / 4 (0.00%)
occurrences (all)	6	3	0
Trismus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Candida infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Catheter site cellulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Diverticulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Influenza			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0

Nail infection			
subjects affected / exposed	3 / 30 (10.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	1 / 30 (3.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Oral herpes			
subjects affected / exposed	2 / 30 (6.67%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Paronychia			
subjects affected / exposed	4 / 30 (13.33%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	6	2	0
Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Skin infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	4 / 30 (13.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Urinary tract infection			
subjects affected / exposed	1 / 30 (3.33%)	5 / 15 (33.33%)	2 / 4 (50.00%)
occurrences (all)	1	5	2
Urinary tract infection bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	11 / 30 (36.67%)	5 / 15 (33.33%)	2 / 4 (50.00%)
occurrences (all)	11	5	2
Dehydration			
subjects affected / exposed	4 / 30 (13.33%)	4 / 15 (26.67%)	4 / 4 (100.00%)
occurrences (all)	4	4	6
Fluid overload			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	8 / 30 (26.67%)	3 / 15 (20.00%)	1 / 4 (25.00%)
occurrences (all)	9	3	1
Hypercholesterolaemia			

subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 15 (13.33%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Hyperkalaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
subjects affected / exposed	28 / 30 (93.33%)	13 / 15 (86.67%)	4 / 4 (100.00%)
occurrences (all)	49	19	5
Hypertriglyceridaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Hypocalcaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 15 (13.33%)	1 / 4 (25.00%)
occurrences (all)	1	3	1
Hypomagnesaemia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	8 / 30 (26.67%)	4 / 15 (26.67%)	0 / 4 (0.00%)
occurrences (all)	14	5	0
Hypophosphataemia			

subjects affected / exposed	5 / 30 (16.67%)	2 / 15 (13.33%)	2 / 4 (50.00%)
occurrences (all)	7	2	2
Malnutrition			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 15 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vitamin D deficiency			
subjects affected / exposed	4 / 30 (13.33%)	1 / 15 (6.67%)	0 / 4 (0.00%)
occurrences (all)	4	1	0

Non-serious adverse events	Part 1: Continuous pemigatinib 10 mg BID	Part 3: Gem/Cis/intermittent pemigatinib 9 mg	Part 3: Gem/Cis/intermittent pemigatinib 13.5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	1 / 1 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyogenic granuloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Systolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	5 / 7 (71.43%)
occurrences (all)	0	0	5
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	2 / 3 (66.67%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Swelling face			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast fibrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Dyspnoea exertional			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			

subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	4 / 7 (57.14%)
occurrences (all)	0	0	10
Amylase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	4 / 7 (57.14%)
occurrences (all)	0	0	9
Blood 1,25-dihydroxycholecalciferol decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood 1,25-dihydroxycholecalciferol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood 25-hydroxycholecalciferol decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	4 / 7 (57.14%)
occurrences (all)	0	1	6
Blood folate decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	4
Blood phosphorus increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	4
Neutrophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	3
Urine analysis abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	3 / 7 (42.86%)
occurrences (all)	0	2	5
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip injury			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail avulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vocal cord paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 1 (100.00%)	7 / 7 (100.00%)
occurrences (all)	1	1	8
Iron deficiency anaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Lymph node pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Microcytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	4 / 7 (57.14%)
occurrences (all)	0	0	9
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	4 / 7 (57.14%)
occurrences (all)	0	1	9
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract cortical			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chorioretinopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry age-related macular degeneration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Entropion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Iridocyclitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Keratopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ocular hypertension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ocular surface disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal degeneration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal fovea disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Scleral discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scleral hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Trichiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ulcerative keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Visual acuity reduced			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreoretinal traction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Abdominal pain lower			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Abdominal tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Angular cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chapped lips			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	4 / 7 (57.14%)
occurrences (all)	0	0	4
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	4 / 7 (57.14%)
occurrences (all)	2	0	7
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	3 / 3 (100.00%)	1 / 1 (100.00%)	2 / 7 (28.57%)
occurrences (all)	3	1	2
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Dysphagia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	4 / 7 (57.14%)
occurrences (all)	0	1	4
Oesophageal hypomotility			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	3 / 3 (100.00%)	1 / 1 (100.00%)	2 / 7 (28.57%)
occurrences (all)	5	1	2
Tongue erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	5
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail bed bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nail hypertrophy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Onychomadesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraneoplastic pemphigus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Autoimmune nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower urinary tract symptoms			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoparathyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Trismus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Eye infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 3 (66.67%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Dehydration			

subjects affected / exposed	1 / 3 (33.33%)	1 / 1 (100.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Fluid overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Hyperphosphataemia			
subjects affected / exposed	3 / 3 (100.00%)	1 / 1 (100.00%)	3 / 7 (42.86%)
occurrences (all)	5	1	6
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 1 (100.00%)	2 / 7 (28.57%)
occurrences (all)	2	2	3
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 1 (100.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 1 (100.00%)	3 / 7 (42.86%)
occurrences (all)	2	1	3
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 3: Tras/intermittent pemigatinib 13.5 mg	Part 3: Doc/intermittent pemigatinib 13.5 mg	Part 3: Pem/intermittent pemigatinib 9 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	7 / 7 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cancer pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyogenic granuloma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	2 / 7 (28.57%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Systolic hypertension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Thrombophlebitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Catheter site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)	5 / 7 (71.43%)	1 / 3 (33.33%)
occurrences (all)	2	6	1
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	2 / 7 (28.57%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Performance status decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			

Breast fibrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	4 / 6 (66.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Dysphonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	2 / 6 (33.33%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	2 / 6 (33.33%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Confusional state			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Disorientation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood 1,25-dihydroxycholecalciferol decreased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Blood 1,25-dihydroxycholecalciferol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood 25-hydroxycholecalciferol decreased			

subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Blood folate decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lip injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail avulsion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound complication			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	0 / 6 (0.00%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Headache			
subjects affected / exposed	2 / 6 (33.33%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Hyperaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Taste disorder			

subjects affected / exposed	2 / 6 (33.33%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 6 (33.33%)	3 / 7 (42.86%)	1 / 3 (33.33%)
occurrences (all)	2	3	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Microcytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract cortical			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			

subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cataract subcapsular			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Chorioretinopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry age-related macular degeneration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	2 / 6 (33.33%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Entropion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Keratopathy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lacrimation decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ocular hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular surface disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal degeneration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal fovea disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scleral discolouration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scleral hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trichiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ulcerative keratitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 6 (16.67%)	2 / 7 (28.57%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Visual acuity reduced			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vitreoretinal traction syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Chapped lips			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 6 (33.33%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	2	4	0
Diarrhoea			
subjects affected / exposed	3 / 6 (50.00%)	6 / 7 (85.71%)	1 / 3 (33.33%)
occurrences (all)	3	13	1
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	4 / 6 (66.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Dyspepsia			
subjects affected / exposed	2 / 6 (33.33%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Glossodynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	4 / 7 (57.14%)	0 / 3 (0.00%)
occurrences (all)	2	6	0
Oesophageal hypomotility			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Oesophageal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	2 / 6 (33.33%)	2 / 7 (28.57%)	1 / 3 (33.33%)
occurrences (all)	2	2	1
Tongue erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	3 / 7 (42.86%)	1 / 3 (33.33%)
occurrences (all)	0	5	1
Hepatobiliary disorders			
Hyperbilirubinaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	5 / 6 (83.33%)	3 / 7 (42.86%)	0 / 3 (0.00%)
occurrences (all)	5	4	0
Decubitus ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eczema asteatotic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Hypertrichosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail bed bleeding			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nail discolouration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nail hypertrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Onychomadesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Paraneoplastic pemphigus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Autoimmune nephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lower urinary tract symptoms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Micturition urgency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperparathyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoparathyroidism			

subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Muscle tightness			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Trismus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Body tinea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nail infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 7 (28.57%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	3 / 6 (50.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tinea pedis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	2 / 6 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 6 (50.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	4 / 7 (57.14%)	1 / 3 (33.33%)
occurrences (all)	0	7	1
Fluid overload			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Hypercholesterolaemia			

subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hyperphosphataemia			
subjects affected / exposed	5 / 6 (83.33%)	6 / 7 (85.71%)	3 / 3 (100.00%)
occurrences (all)	9	7	4
Hypertriglyceridaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 7 (28.57%)	1 / 3 (33.33%)
occurrences (all)	0	3	2
Hypophosphataemia			

subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2

Non-serious adverse events	Part 3: Pem/intermittent pemigatinib 13.5 mg	Part 3: Pem/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 9 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	9 / 9 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pyogenic granuloma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Systolic hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Catheter site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chills			

subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	5 / 14 (35.71%)	1 / 9 (11.11%)	3 / 7 (42.86%)
occurrences (all)	5	1	3
Gait disturbance			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Generalised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 14 (7.14%)	3 / 9 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Swelling face			

subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tenderness			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast fibrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	4 / 14 (28.57%)	2 / 9 (22.22%)	0 / 7 (0.00%)
occurrences (all)	4	2	0
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	3 / 14 (21.43%)	1 / 9 (11.11%)	2 / 7 (28.57%)
occurrences (all)	3	1	2
Dyspnoea exertional			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nasal septum deviation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sinus disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Disorientation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Restlessness			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	5 / 14 (35.71%)	3 / 9 (33.33%)	0 / 7 (0.00%)
occurrences (all)	9	4	0
Amylase increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 14 (35.71%)	3 / 9 (33.33%)	0 / 7 (0.00%)
occurrences (all)	10	4	0
Blood 1,25-dihydroxycholecalciferol decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood 1,25-dihydroxycholecalciferol increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood 25-hydroxycholecalciferol decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 14 (14.29%)	3 / 9 (33.33%)	0 / 7 (0.00%)
occurrences (all)	5	4	0
Blood bilirubin increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood creatine increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	4 / 14 (28.57%)	1 / 9 (11.11%)	1 / 7 (14.29%)
occurrences (all)	7	1	2
Blood folate decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Computerised tomogram abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 decreased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vitamin D decreased			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Vitamin D increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Weight increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
White blood cell count increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Infusion related reaction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lip injury			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail avulsion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	2 / 9 (22.22%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Dysarthria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 9 (11.11%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Headache			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	3
Hyperaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Presyncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	2 / 14 (14.29%)	3 / 9 (33.33%)	2 / 7 (28.57%)
occurrences (all)	3	3	2
Tremor			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 14 (50.00%)	3 / 9 (33.33%)	2 / 7 (28.57%)
occurrences (all)	10	4	2
Iron deficiency anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blepharospasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract cortical			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Cataract nuclear			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chorioretinopathy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry age-related macular degeneration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	4 / 14 (28.57%)	4 / 9 (44.44%)	0 / 7 (0.00%)
occurrences (all)	4	4	0
Entropion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Growth of eyelashes			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0

Iridocyclitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Keratopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Macular fibrosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ocular hypertension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ocular surface disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Photophobia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pterygium			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal degeneration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Retinal detachment			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Retinal disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Retinal fovea disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retinal oedema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Scleral discolouration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scleral hyperaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Subretinal fluid			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Trichiasis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Ulcerative keratitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	3 / 14 (21.43%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Visual acuity reduced			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Vitreoretinal traction syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	2 / 14 (14.29%)	2 / 9 (22.22%)	0 / 7 (0.00%)
occurrences (all)	7	2	0
Abdominal pain lower			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Abdominal tenderness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Chapped lips			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	5 / 14 (35.71%)	1 / 9 (11.11%)	1 / 7 (14.29%)
occurrences (all)	7	1	1
Diarrhoea			
subjects affected / exposed	7 / 14 (50.00%)	3 / 9 (33.33%)	3 / 7 (42.86%)
occurrences (all)	17	7	6
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	4 / 14 (28.57%)	5 / 9 (55.56%)	4 / 7 (57.14%)
occurrences (all)	5	5	4
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysphagia			

subjects affected / exposed	3 / 14 (21.43%)	1 / 9 (11.11%)	3 / 7 (42.86%)
occurrences (all)	3	1	4
Eructation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Loose tooth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 14 (21.43%)	3 / 9 (33.33%)	2 / 7 (28.57%)
occurrences (all)	8	3	4
Oesophageal hypomotility			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oesophageal stenosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oesophageal ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oral dysaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Paraesthesia oral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rectal tenesmus			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	5 / 14 (35.71%)	3 / 9 (33.33%)	4 / 7 (57.14%)
occurrences (all)	7	4	5
Tongue erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	3 / 14 (21.43%)	3 / 9 (33.33%)	2 / 7 (28.57%)
occurrences (all)	5	3	4
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	6 / 14 (42.86%)	5 / 9 (55.56%)	1 / 7 (14.29%)
occurrences (all)	6	5	1
Decubitus ulcer			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Madarosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nail bed bleeding			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail bed tenderness			
subjects affected / exposed	0 / 14 (0.00%)	2 / 9 (22.22%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Nail discolouration			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nail hypertrophy			

subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nail ridging			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Onychoclasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	1 / 14 (7.14%)	2 / 9 (22.22%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Onychomadesis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Pain of skin			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	2 / 14 (14.29%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	2	3	0
Paraneoplastic pemphigus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	3 / 14 (21.43%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Rash papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Skin fissures			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Autoimmune nephritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Lower urinary tract symptoms			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoparathyroidism			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Thyroiditis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 14 (28.57%)	2 / 9 (22.22%)	0 / 7 (0.00%)
occurrences (all)	7	2	0
Arthritis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Back pain			

subjects affected / exposed	2 / 14 (14.29%)	1 / 9 (11.11%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Muscle tightness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Osteonecrosis of jaw			

subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Trismus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Candida infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	2 / 9 (22.22%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Diverticulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Eye infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	3
Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Pharyngitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	3 / 9 (33.33%)	2 / 7 (28.57%)
occurrences (all)	1	5	4
Urinary tract infection bacterial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	9 / 14 (64.29%)	2 / 9 (22.22%)	1 / 7 (14.29%)
occurrences (all)	11	2	1
Dehydration			

subjects affected / exposed	2 / 14 (14.29%)	1 / 9 (11.11%)	3 / 7 (42.86%)
occurrences (all)	3	1	3
Fluid overload			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	4 / 14 (28.57%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	6	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	4	0	1
Hyperkalaemia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Hyperphosphataemia			
subjects affected / exposed	11 / 14 (78.57%)	5 / 9 (55.56%)	4 / 7 (57.14%)
occurrences (all)	41	7	4
Hypertriglyceridaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypocalcaemia			

subjects affected / exposed	2 / 14 (14.29%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 9 (0.00%)	2 / 7 (28.57%)
occurrences (all)	4	0	2
Hypomagnesaemia			
subjects affected / exposed	5 / 14 (35.71%)	0 / 9 (0.00%)	3 / 7 (42.86%)
occurrences (all)	5	0	3
Hyponatraemia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Hypophosphataemia			
subjects affected / exposed	3 / 14 (21.43%)	1 / 9 (11.11%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Malnutrition			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Metabolic acidosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 9 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 3: Ref/continuous pemigatinib 13.5 mg	Part 3: Ref/continuous pemigatinib 20 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	2 / 2 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cancer pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Melanocytic naevus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Metastases to central nervous system			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pyogenic granuloma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin papilloma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	
occurrences (all)	2	1	
Systolic hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Thrombophlebitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Venous thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	2	
Catheter site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	2	
Fatigue			
subjects affected / exposed	6 / 9 (66.67%)	0 / 2 (0.00%)	
occurrences (all)	10	0	
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Generalised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			

subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Performance status decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	2	
Swelling face			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tenderness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Drug hypersensitivity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypersensitivity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			

Breast fibrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Dysphonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasal dryness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasal septum deviation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Paranasal sinus discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pharyngeal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pulmonary embolism			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Rales			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Respiratory tract congestion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Rhonchi			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sinus disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sinus pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Sneezing			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Confusional state			

subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Disorientation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Restlessness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Amylase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	4	0	
Blood 1,25-dihydroxycholecalciferol decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood 1,25-dihydroxycholecalciferol increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood 25-hydroxycholecalciferol decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Blood alkaline phosphatase increased				
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)		
occurrences (all)	2	0		
Blood bilirubin increased				
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)		
occurrences (all)	1	0		
Blood creatine increased				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Blood creatinine increased				
subjects affected / exposed	2 / 9 (22.22%)	2 / 2 (100.00%)		
occurrences (all)	5	4		
Blood folate decreased				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Blood glucose increased				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Blood phosphorus increased				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Blood thyroid stimulating hormone decreased				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Blood uric acid increased				
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)		
occurrences (all)	0	1		
Computerised tomogram abnormal				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Gamma-glutamyltransferase increased				

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neutrophil count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urine analysis abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitamin B12 decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitamin D decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitamin D increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	
occurrences (all)	2	1	
Weight increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
White blood cell count decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
White blood cell count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Limb injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lip injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nail avulsion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin abrasion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Wound complication			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nodal rhythm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Dysarthria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			

subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Headache			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	
occurrences (all)	2	1	
Hyperaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Restless legs syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Taste disorder			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vocal cord paralysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Leukopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lymph node pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Microcytic anaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Deafness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ear congestion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Excessive cerumen production			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blepharospasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cataract			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cataract cortical			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cataract nuclear			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cataract subcapsular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Chorioretinopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Conjunctival haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Corneal epithelium defect			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Diplopia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dry age-related macular degeneration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dry eye			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Entropion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye discharge			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye irritation			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Eye pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eyelid function disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eyelid pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eyelid ptosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Growth of eyelashes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Iridocyclitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Keratitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Keratopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lacrimation decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lacrimation increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Macular fibrosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Meibomian gland dysfunction				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Ocular discomfort				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Ocular hyperaemia				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Ocular hypertension				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Ocular surface disease				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Periorbital oedema				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Photophobia				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Photopsia				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Pterygium				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Punctate keratitis				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Retinal degeneration				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Retinal detachment				

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Retinal disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Retinal fovea disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Retinal oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Scleral discolouration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Scleral hyperaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Subretinal fluid			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Trichiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ulcerative keratitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Visual acuity reduced			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitreoretinal traction syndrome			

subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Vitreous detachment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitreous floaters			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Abdominal tenderness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Angular cheilitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Chapped lips			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	4	0	
Diarrhoea			
subjects affected / exposed	3 / 9 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	6	1	
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	3 / 9 (33.33%)	2 / 2 (100.00%)	
occurrences (all)	3	2	
Dyspepsia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Dysphagia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Eructation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Flatulence			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gingival pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	

Glossodynia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haematochezia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hiatus hernia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperaesthesia teeth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia oral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lip ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Loose tooth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Mouth ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Oesophageal hypomotility			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Oesophageal stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oesophageal ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oral dysaesthesia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Oral pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Paraesthesia oral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rectal tenesmus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	7 / 9 (77.78%)	1 / 2 (50.00%)	
occurrences (all)	10	1	
Tongue erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tooth disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Hepatobiliary disorders			
Hyperbilirubinaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Portal vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	3 / 9 (33.33%)	2 / 2 (100.00%)	
occurrences (all)	3	2	
Decubitus ulcer			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Dry skin			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Ecchymosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eczema asteatotic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperkeratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Hypertrichosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lichenoid keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Madarosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nail bed bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nail bed tenderness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nail discolouration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nail hypertrophy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nail ridging			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Onychoclasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Onycholysis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Onychomadesis			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Pain of skin			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	

Palmar-plantar erythrodysaesthesia syndrome				
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)		
occurrences (all)	3	0		
Paraneoplastic pemphigus				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Pruritus				
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)		
occurrences (all)	1	0		
Psoriasis				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Rash				
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)		
occurrences (all)	1	0		
Rash maculo-papular				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Rash papular				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Rash pruritic				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Skin fissures				
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)		
occurrences (all)	1	0		
Skin induration				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Skin irritation				
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)		
occurrences (all)	0	0		
Skin lesion				

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitiligo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Autoimmune nephritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Bladder pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Bladder spasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Lower urinary tract symptoms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Micturition urgency			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Nephrolithiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nocturia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Urinary retention			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Urinary tract obstruction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Urinary tract pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperparathyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypoparathyroidism			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Thyroiditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	
occurrences (all)	3	1	
Arthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Bone pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Muscle tightness			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Osteoarthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Osteonecrosis of jaw			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Trismus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Body tinea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Bronchitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Candida infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Catheter site cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Herpes ophthalmic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Nail infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tinea pedis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tinea versicolour			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tooth infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	

Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vaginal infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Decreased appetite			
subjects affected / exposed	3 / 9 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	6	1	
Dehydration			
subjects affected / exposed	3 / 9 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	6	1	
Fluid overload			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Fluid retention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Glucose tolerance impaired			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Hypercholesterolaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperphosphataemia			
subjects affected / exposed	5 / 9 (55.56%)	2 / 2 (100.00%)	
occurrences (all)	9	4	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Hyperuricaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Hypoalbuminaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Hypomagnesaemia			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	
occurrences (all)	2	1	
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			

subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Malnutrition			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Metabolic acidosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vitamin D deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 November 2014	The objective of this amendment was to address the Food and Drug Administration's (FDA's) November 17, 2014, clinical deficiencies.
11 June 2015	The objective of this amendment was to refine procedural language regarding pharmacokinetics (PK) and food effect, ophthalmologic examination frequency, electrocardiogram (ECG) monitoring, and biopsy requirements.
02 November 2015	The primary purpose of this amendment was to add Part 3, Combination Therapy. In Part 3, INCB054828 was paired with 3 different treatment regimens that were already being used for cancer treatment. The amendment also contained changes to the inclusion/exclusion criteria and corrections to the Schedule of Assessment tables.
09 March 2016	The primary purpose of this amendment was to adjust language in the protocol to allow more flexibility for enrollment based on accumulated safety data. The secondary purpose was to adjust the management guidelines for hyperphosphatemia (HP).
27 September 2016	The primary purpose of this amendment was to revise the study design in order to add a continuous dosing cohort, a trastuzumab combination cohort in Part 3, and a lower dose level cohort in Part 1 and Part 3 with mandatory biopsies, and to increase the number of participants in the study.
26 June 2017	The primary purpose of this amendment was to increase the number of participants in Part 2 and make changes to clarify and/or simplify the study design.
10 August 2018	The protocol was updated to include 1) a new combination treatment arm, 2) a renally impaired treatment arm, and 3) mandatory biopsies.
11 December 2018	Changes were made to the protocol based on FDA feedback after review of Amendment 7. Additional changes included the modification of ECG sampling times and the addition of a 4.5-milligram (mg) tablet across all sites/countries.
02 July 2019	The amendment added a twice daily (BID) dosing regimen and updated the clinical experience section.
27 March 2020	The amendment incorporated administrative changes and included updated language for comprehensive eye examination, per FDA feedback.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported