Clinical trial results:
A Phase 2, Open-Label, Single-Agent, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib (INCB054828) in Subjects With Metastatic or Surgically Unresectable Urothelial Carcinoma Harboring FGF/FGFR Alterations - (FIGHT-201)

Summary

EudraCT number	2016-001321-14
Trial protocol	GB BE FR ES NL
Global end of trial date	01 February 2022

Results information

Result version number	v2 (current)
This version publication date	09 April 2023
First version publication date	20 February 2023
Version creation reason	• Correction of full data set Revisions made to align with ClinicalTrials.gov record after undergoing NIH review.

Trial information

Trial identification

Sponsor protocol code	INCB 54828-201

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	01 February 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 February 2022
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 overall response rate (ORR) of pemigatinib as a monotherapy in the treatment of metastatic or surgically unresectable urothelial carcinoma harboring fibroblast growth factor/fibroblast growth factor receptor (FGF/FGFR) alterations.

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 11, 50, 54, 56, and 312, as well as International Conference on Harmonisation Good Clinical Practice (ICH GCP) consolidated guidelines (E6), Japanese-Good Clinical Practice (J-GCP), and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 January 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 64
Country: Number of subjects enrolled	Israel: 15
Country: Number of subjects enrolled	Japan: 10
Country: Number of subjects enrolled	United States: 78
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	Italy: 36
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Spain: 17
Country: Number of subjects enrolled	Belgium: 14
Country: Number of subjects enrolled	Denmark: 3
Country: Number of subjects enrolled	United Kingdom: 11
Worldwide total number of subjects	260
EEA total number of subjects	146

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)	91
From 65 to 84 years	164
85 years and over	5

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted at a total of 73 study centers in 11 countries (United States, France, Italy, Spain, Israel, Belgium, United Kingdom, Germany, Japan, Denmark, and the Netherlands).

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	Cohort A-ID: FGFR3 mutations or fusions

Arm description:

Participants with fibroblast growth factor (FGF) receptor 3 (FGFR3) mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 milligrams (mg) once daily (QD) on an intermittent dose (ID) (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/deciliter (dL) could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related treatment-emergent adverse events (TEAEs), and they had been compliant with taking the study drug.

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:

2.0- and 4.5-mg tablets; starting dose of 13.5 mg

Arm title	Cohort B-ID: All other FGF/FGFR alterations

Arm description:

Participants with all other FGF/FGFR alterations self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

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:

2.0- and 4.5-mg tablets; starting dose of 13.5 mg

Arm title	Other-ID

Arm description:

Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-

related TEAEs, and they had been compliant with taking the study drug.

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:

2.0- and 4.5-mg tablets; starting dose of 13.5 mg

Arm title	Cohort A-CD: FGFR3 mutations or fusions

Arm description:

Participants with FGFR3 mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

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:

2.0- and 4.5-mg tablets; starting dose of 13.5 mg

Arm title	Other-CD

Arm description:

Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

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:

2.0- and 4.5-mg tablets; starting dose of 13.5 mg

Number of subjects in period 1	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID
Started	103	44	9
Completed	10	2	1
Not completed	93	42	8
Adverse event, serious fatal	87	36	8
Consent withdrawn by subject	1	3	-
Physician decision	-	-	-

Captured as Other	2	-	-
Progressive Disease	1	2	-
Lost to follow-up	2	1	-

Number of subjects in period 1	Cohort A-CD: FGFR3 mutations or fusions	Other-CD
Started	101	3
Completed	13	1
Not completed	88	2
Adverse event, serious fatal	81	2
Consent withdrawn by subject	2	-
Physician decision	1	-
Captured as Other	1	-
Progressive Disease	-	-
Lost to follow-up	3	-

Baseline characteristics

Reporting groups	
Reporting group title	Cohort A-ID: FGFR3 mutations or fusions
Reporting group description:	
Participants with fibroblast growth factor (FGF) receptor 3 (FGFR3) mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 milligrams (mg) once daily (QD) on an intermittent dose (ID) (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/deciliter (dL) could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related treatment-emergent adverse events (TEAEs), and they had been compliant with taking the study drug.	
Reporting group title	Cohort B-ID: All other FGF/FGFR alterations
Reporting group description:	
Participants with all other FGF/FGFR alterations self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.	
Reporting group title	Other-ID
Reporting group description:	
Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.	
Reporting group title	Cohort A-CD: FGFR3 mutations or fusions
Reporting group description:	
Participants with FGFR3 mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.	
Reporting group title	Other-CD
Reporting group description:	
Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.	

Reporting group values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID
Number of subjects	103	44	9
Age categorical Units: Subjects			
Adults (18-64 years)	40	19	3
From 65-84 years	60	25	6
85 years and over	3	0	0
Age Continuous Units: years			
arithmetic mean	67.6	65.1	69.3
standard deviation	± 9.09	± 10.83	± 7.98
Sex: Female, Male Units: participants			
Female	29	14	1

Male	74	30	8

Race, Customized Units: Subjects			
White	64	29	6
Black or African-American	0	0	1
Asian	2	2	0
Turkish	1	0	0
Persian	0	0	1
Unknown or Not Reported	30	13	1
Missing	6	0	0
Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	64	32	7
Not Reported	23	11	2
Unknown	5	1	0
Captured as Other	5	0	0
Missing	5	0	0

Reporting group values	Cohort A-CD: FGFR3 mutations or fusions	Other-CD	Total
Number of subjects	101	3	260
Age categorical Units: Subjects			
Adults (18-64 years)	27	2	91
From 65-84 years	72	1	164
85 years and over	2	0	5
Age Continuous Units: years			
arithmetic mean	68.5	60.3	
standard deviation	± 9.39	± 9.02	-
Sex: Female, Male Units: participants			
Female	23	1	68
Male	78	2	192
Race, Customized Units: Subjects			
White	63	2	164
Black or African-American	0	0	1
Asian	12	1	17
Turkish	0	0	1
Persian	0	0	1
Unknown or Not Reported	22	0	66
Missing	4	0	10
Ethnicity, Customized Units: Subjects			
Hispanic or Latino	2	0	3
Not Hispanic or Latino	66	2	171
Not Reported	22	1	59
Unknown	3	0	9

Captured as Other	6	0	11
Missing	2	0	7

End points

End points reporting groups

Reporting group title	Cohort A-ID: FGFR3 mutations or fusions

Reporting group description:

Participants with fibroblast growth factor (FGF) receptor 3 (FGFR3) mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 milligrams (mg) once daily (QD) on an intermittent dose (ID) (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/deciliter (dL) could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related treatment-emergent adverse events (TEAEs), and they had been compliant with taking the study drug.

Reporting group title	Cohort B-ID: All other FGF/FGFR alterations

Reporting group description:

Participants with all other FGF/FGFR alterations self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Reporting group title	Other-ID

Reporting group description:

Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Reporting group title	Cohort A-CD: FGFR3 mutations or fusions

Reporting group description:

Participants with FGFR3 mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Reporting group title	Other-CD

Reporting group description:

Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Subject analysis set title	Cohort A-ID + Cohort B-ID
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with FGFR3 mutations or fusions (Cohort A) or with all other FGF/FGFR alterations (Cohort B) self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Subject analysis set title	Cohort A-ID + Cohort A-CD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with FGFR3 mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule (Cohort A-ID) or on a CD (no planned dose hold) schedule (Cohort A-CD) in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Subject analysis set title	Cohort A-ID + Cohort B-ID + Cohort A-CD
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with FGFR3 mutations or fusions (Cohort A) or with all other FGF/FGFR alterations (Cohort B) self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule (Cohort A-ID and Cohort B-ID) in 21-day cycles or on a CD (no planned dose hold) schedule (Cohort A-CD). Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Primary: Objective Response Rate (ORR) in participants with FGFR3 mutations or fusions on a CD regimen

End point title	Objective Response Rate (ORR) in participants with FGFR3 mutations or fusions on a CD regimen[1]

End point description:

ORR was defined as the percentage of participants with a best overall response of complete response (CR) or partial response (PR) at any post-Baseline visit prior to first progressive disease (PD), per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 (v1.1). 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. FGFR/FGF status was based on central genomics laboratory results. Response was based on review of scans by an independent centralized radiological review committee. Response was confirmed.

End point type	Primary

End point timeframe:

up to 1138 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.

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[2]	0[3]	0[4]	101
Units: percentage of participants				
number (confidence interval 95%)	(to)	(to)	(to)	17.8 (10.92 to 26.70)

Notes:

[2] - Analysis was conducted in participants with FGFR3 mutations or fusions on a CD regimen.

[3] - Analysis was conducted in participants with FGFR3 mutations or fusions on a CD regimen.

[4] - Analysis was conducted in participants with FGFR3 mutations or fusions on a CD regimen.

End point values	Other-CD			
Subject group type	Reporting group			
Number of subjects analysed	0[5]			
Units: percentage of participants				
number (confidence interval 95%)	(to)			

Notes:

[5] - Analysis was conducted in participants with FGFR3 mutations or fusions on a CD regimen.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR in participants with FGFR3 mutations or fusions on an ID regimen

End point title	ORR in participants with FGFR3 mutations or fusions on an ID regimen

End point description:

ORR was defined as the percentage of participants with a best overall response of CR or PR at any post-Baseline visit prior to first PD, per RECIST v1.1. 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. FGFR/FGF status was based on central genomics laboratory results. Response was based on review of scans by an independent centralized radiological review committee. Response was confirmed.

End point type	Secondary

End point timeframe:

up to 817 days

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	103	0[6]	0[7]	0[8]
Units: percentage of participants				
number (confidence interval 95%)	23.3 (15.54 to 32.66)	(to)	(to)	(to)

Notes:

[6] - Analysis was conducted in participants with FGFR3 mutations or fusions on an ID regimen.

[7] - Analysis was conducted in participants with FGFR3 mutations or fusions on an ID regimen.

[8] - Analysis was conducted in participants with FGFR3 mutations or fusions on an ID regimen.

End point values	Other-CD			
Subject group type	Reporting group			
Number of subjects analysed	0[9]			
Units: percentage of participants				
number (confidence interval 95%)	(to)			

Notes:

[9] - Analysis was conducted in participants with FGFR3 mutations or fusions on an ID regimen.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR in participants with all other FGF/FGFR alterations

End point title	ORR in participants with all other FGF/FGFR alterations

End point description:

ORR was defined as the percentage of participants with a best overall response of CR or PR at any post-Baseline visit prior to first PD, per RECIST v1.1. 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. FGFR/FGF status was based on central genomics laboratory results. Response was based on review of scans by an independent centralized radiological review committee. Response was confirmed.

End point type	Secondary

End point timeframe:

up to 1198 days

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[10]	44	0[11]	0[12]
Units: percentage of participants				
number (confidence interval 95%)	(to)	6.8 (1.43 to 18.66)	(to)	(to)

Notes:

[10] - Analysis was conducted in participants with all other FGF/FGFR alterations.

[11] - Analysis was conducted in participants with all other FGF/FGFR alterations.

[12] - Analysis was conducted in participants with all other FGF/FGFR alterations.

End point values	Other-CD			
Subject group type	Reporting group			
Number of subjects analysed	0[13]			
Units: percentage of participants				
number (confidence interval 95%)	(to)			

Notes:

[13] - Analysis was conducted in participants with all other FGF/FGFR alterations.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR in all participants on an ID or CD regimen in combined cohorts

End point title	ORR in all participants on an ID or CD regimen in combined cohorts

End point description:

ORR was defined as the percentage of participants with a best overall response of CR or PR at any post-Baseline visit prior to first PD, per RECIST v1.1. 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. FGFR/FGF status was based on central genomics laboratory results. Response was based on review of scans by an independent centralized radiological review committee. Response was confirmed.

End point type	Secondary

End point timeframe:

up to 1198 days

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[14]	0[15]	0[16]	0[17]
Units: percentage of participants				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[14] - Analysis was conducted in participants on an ID or CD regimen in combined cohorts.

[15] - Analysis was conducted in participants on an ID or CD regimen in combined cohorts.

[16] - Analysis was conducted in participants on an ID or CD regimen in combined cohorts.

[17] - Analysis was conducted in participants on an ID or CD regimen in combined cohorts.

End point values	Other-CD	Cohort A-ID + Cohort B-ID	Cohort A-ID + Cohort A-CD	Cohort A-ID + Cohort B-ID + Cohort A-CD
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[18]	147	204	248
Units: percentage of participants				
number (confidence interval 95%)	(to)	18.4 (12.47 to 25.59)	20.6 (15.26 to 26.79)	18.1 (13.55 to 23.52)

Notes:

[18] - Analysis was conducted in participants on an ID or CD regimen in combined cohorts.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any treatment-emergent adverse event (TEAE)

End point title	Number of participants with any treatment-emergent adverse event (TEAE)

End point description:

An adverse event (AE) was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring 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). A TEAE was any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug and within 30 days of the last dose of study drug.

End point type	Secondary

End point timeframe:

up to approximately 25 weeks

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	103	44	9	101
Units: participants	103	44	9	100

End point values	Other-CD			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: participants	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

End point title	Progression-free Survival (PFS)

End point description:

PFS was defined as the length of time from the start of the study drug (Day 1) to the earlier of death or disease progression by RECIST v1.1, as assessed by the independent centralized radiological review committee.

End point type	Secondary

End point timeframe:

up to 1138 days

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	103	44	0[19]	101
Units: months				
median (confidence interval 95%)	4.27 (3.91 to 6.05)	2.04 (1.87 to 2.17)	(to)	4.04 (3.45 to 4.17)

Notes:

[19] - The "Other-ID" treatment group was not included in the Efficacy Evaluable Population.

End point values	Other-CD			
Subject group type	Reporting group			
Number of subjects analysed	0[20]			
Units: months				
median (confidence interval 95%)	(to)			

Notes:

[20] - The "Other-CD" treatment group was not included in the Efficacy Evaluable Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

DOR was defined as the time from the first overall response contributing to an objective response (CR or PR) to the earlier of death or first overall response of PD occurring after the first overall response contributing to the objective response. 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. 9999 = The upper limit of the confidence interval was not estimable because too few participants had disease progression or died. Only participants with a CR or PR were analyzed. Response was based on review of scans by an independent centralized radiological review committee. Response was confirmed.

End point type	Secondary

End point timeframe:

up to 1075 days

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	3	0[21]	18
Units: months				
median (confidence interval 95%)	6.21 (4.60 to 7.95)	10.02 (8.38 to 9999)	(to)	6.23 (4.14 to 8.25)

Notes:

[21] - The "Other-ID" treatment group was not included in the Efficacy Evaluable Population.

End point values	Other-CD			
Subject group type	Reporting group			
Number of subjects analysed	0[22]			
Units: months				
median (confidence interval 95%)	(to)			

Notes:

[22] - The "Other-CD" treatment group was not included in the Efficacy Evaluable Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival

End point description:

Overall survival was defined as the length of time from the start of the study drug (Day 1) until the date of death due to any cause.

End point type	Secondary

End point timeframe:

up to 1610 days

End point values	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID	Cohort A-CD: FGFR3 mutations or fusions
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	103	44	0[23]	101
Units: months				
median (confidence interval 95%)	8.90 (7.46 to 15.18)	9.13 (5.52 to 17.05)	(to)	6.80 (5.26 to 9.10)

Notes:

[23] - The "Other-ID" treatment group was not included in the Efficacy Evaluable Population.

End point values	Other-CD			
Subject group type	Reporting group			
Number of subjects analysed	0[24]			
Units: months				
median (confidence interval 95%)	(to)			

Notes:

[24] - The "Other-CD" treatment group was not included in the Efficacy Evaluable Population.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were assessed for up to approximately 25 weeks; All-cause Mortality was assessed for up to 1610 days.

Adverse event reporting additional description:

Treatment-emergent adverse events, 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, have been reported.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

Reporting groups

Reporting group title	Cohort A-ID: FGFR3 mutations or fusions

Reporting group description:

Participants with fibroblast growth factor (FGF) receptor 3 (FGFR3) mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 milligrams (mg) once daily (QD) on an intermittent dose (ID) (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/deciliter (dL) could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related treatment-emergent adverse events (TEAEs), and they had been compliant with taking the study drug.

Reporting group title	Cohort B-ID: All other FGF/FGFR alterations

Reporting group description:

Participants with all other FGF/FGFR alterations self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Reporting group title	Other-ID

Reporting group description:

Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on an ID (2-weeks-on/1-week-off therapy) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Reporting group title	Cohort A-CD: FGFR3 mutations or fusions

Reporting group description:

Participants with FGFR3 mutations or fusions self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Reporting group title	Other-CD

Reporting group description:

Participants with no FGF/FGFR alterations or with an undetermined FGF/FGFR status self-administered oral pemigatinib at a starting dose of 13.5 mg QD on a continuous dose (CD) (no planned dose hold) schedule in 21-day cycles. Participants who did not reach the target serum phosphate level of > 5.5 mg/dL could have increased the daily dose to 18 mg, provided they had no ongoing Grade 2 or higher treatment-related TEAEs, and they had been compliant with taking the study drug.

Serious adverse events	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID
Total subjects affected by serious adverse events			
subjects affected / exposed	45 / 103 (43.69%)	26 / 44 (59.09%)	3 / 9 (33.33%)
number of deaths (all causes)	88	39	8
number of deaths resulting from adverse events	14	6	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Rectal cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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			
Hypertension			

subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Hypovolaemic shock			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Vasculitis necrotising			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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			
Asthenia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site inflammation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			

subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	5 / 103 (4.85%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 3	0 / 0
Malaise			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Pain			
subjects affected / exposed	0 / 103 (0.00%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyp			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			

subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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			
Cough			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Hiccups			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Hypoxia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Respiratory distress			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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			
Delirium			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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 urine present			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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 creatinine increased			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (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
Hepatic enzyme increased			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Urine output decreased			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
White blood cell count increased			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anastomotic haemorrhage			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Craniocerebral injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Fractured sacrum			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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 fracture			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Stomal hernia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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 stoma complication			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urostomy complication			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (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
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Cardiac failure			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebellar haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Lethargy			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Motor dysfunction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Peripheral nerve paresis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Spinal cord compression			

subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Leukocytosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Chorioretinopathy			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Detachment of retinal pigment epithelium			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuropathy			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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			
subjects affected / exposed	2 / 103 (1.94%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	2 / 103 (1.94%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Diarrhoea			
subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal infarction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 103 (0.97%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic mass			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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	2 / 103 (1.94%)	2 / 44 (4.55%)	0 / 9 (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
Stomatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	1 / 103 (0.97%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Gallbladder enlargement			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin toxicity			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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	3 / 103 (2.91%)	4 / 44 (9.09%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bladder outlet obstruction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Bladder mass			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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 kidney disease			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Haematuria			
subjects affected / exposed	4 / 103 (3.88%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal injury			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Back pain			
subjects affected / exposed	2 / 103 (1.94%)	2 / 44 (4.55%)	0 / 9 (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
Bone pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Intervertebral disc protrusion			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Bacteraemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Bronchitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Empyema			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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 infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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 salmonella			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			

subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 103 (1.94%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Pyelonephritis acute			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Spinal cord infection			

subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	6 / 103 (5.83%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	2 / 103 (1.94%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral oesophagitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	0 / 9 (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
Failure to thrive			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
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	2 / 103 (1.94%)	0 / 44 (0.00%)	0 / 9 (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
Hyperkalaemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Hyperphosphataemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Hypocalcaemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (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
Hyponatraemia			
subjects affected / exposed	0 / 103 (0.00%)	2 / 44 (4.55%)	0 / 9 (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

Serious adverse events	Cohort A-CD: FGFR3 mutations or fusions	Other-CD	
Total subjects affected by serious adverse events			
subjects affected / exposed	48 / 101 (47.52%)	1 / 3 (33.33%)	
number of deaths (all causes)	83	2	
number of deaths resulting from adverse events	16	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Malignant neoplasm progression			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour associated fever			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Phlebitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis necrotising			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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			
Asthenia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Catheter site inflammation			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Fatigue			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	5 / 101 (4.95%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 5	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Malaise			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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 / 101 (0.00%)	0 / 3 (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	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary haemorrhage			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			

subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood urine present			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urine output decreased			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural			

complications				
Anastomotic haemorrhage				
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Craniocerebral injury				
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Fall				
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Fractured sacrum				
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Spinal fracture				
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Stomal hernia				
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Subdural haematoma				
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Urinary tract stoma complication				
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Urostomy complication				

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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			
Cerebellar haemorrhage			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor dysfunction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve paresis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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 / 101 (0.00%)	0 / 3 (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	2 / 101 (1.98%)	1 / 3 (33.33%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Chorioretinopathy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Detachment of retinal pigment epithelium			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic neuropathy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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 distension			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal infarction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass			

subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder enlargement			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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			
Angioedema			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin toxicity			

subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder mass			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal failure			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal injury			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hypercalcaemia of malignancy			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 101 (0.99%)	1 / 3 (33.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intervertebral disc protrusion			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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			
Bacteraemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			

subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			

subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Septic shock			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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	8 / 101 (7.92%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 11	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral oesophagitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (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			
Decreased appetite			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperphosphataemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	1 / 101 (0.99%)	1 / 3 (33.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Cohort A-ID: FGFR3 mutations or fusions	Cohort B-ID: All other FGF/FGFR alterations	Other-ID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	101 / 103 (98.06%)	43 / 44 (97.73%)	9 / 9 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	10 / 103 (9.71%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	11	3	0
Orthostatic hypotension			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	28 / 103 (27.18%)	9 / 44 (20.45%)	2 / 9 (22.22%)
occurrences (all)	31	9	2
Chills			
subjects affected / exposed	2 / 103 (1.94%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	2	3	0
Chest pain			
subjects affected / exposed	2 / 103 (1.94%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
Fatigue			
subjects affected / exposed	36 / 103 (34.95%)	16 / 44 (36.36%)	3 / 9 (33.33%)
occurrences (all)	44	17	3
Influenza like illness			
subjects affected / exposed	2 / 103 (1.94%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	2	2	1
Mucosal inflammation			

subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	2
Oedema peripheral			
subjects affected / exposed	6 / 103 (5.83%)	8 / 44 (18.18%)	0 / 9 (0.00%)
occurrences (all)	6	9	0
Pain			
subjects affected / exposed	6 / 103 (5.83%)	3 / 44 (6.82%)	2 / 9 (22.22%)
occurrences (all)	6	3	2
Pyrexia			
subjects affected / exposed	14 / 103 (13.59%)	6 / 44 (13.64%)	0 / 9 (0.00%)
occurrences (all)	19	6	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	3 / 103 (2.91%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	3	3	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	15 / 103 (14.56%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	18	3	0
Dyspnoea			
subjects affected / exposed	4 / 103 (3.88%)	3 / 44 (6.82%)	1 / 9 (11.11%)
occurrences (all)	4	4	1
Dysphonia			
subjects affected / exposed	5 / 103 (4.85%)	4 / 44 (9.09%)	1 / 9 (11.11%)
occurrences (all)	5	6	1
Epistaxis			
subjects affected / exposed	13 / 103 (12.62%)	3 / 44 (6.82%)	2 / 9 (22.22%)
occurrences (all)	15	3	2
Nasal dryness			
subjects affected / exposed	3 / 103 (2.91%)	0 / 44 (0.00%)	2 / 9 (22.22%)
occurrences (all)	3	0	2
Oropharyngeal pain			
subjects affected / exposed	6 / 103 (5.83%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	7	3	0
Upper-airway cough syndrome			

subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	5 / 103 (4.85%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	6	1	1
Insomnia			
subjects affected / exposed	12 / 103 (11.65%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences (all)	13	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 103 (2.91%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 103 (4.85%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	6	0	0
Blood creatinine increased			
subjects affected / exposed	17 / 103 (16.50%)	5 / 44 (11.36%)	2 / 9 (22.22%)
occurrences (all)	19	5	2
Blood phosphorus increased			
subjects affected / exposed	9 / 103 (8.74%)	4 / 44 (9.09%)	2 / 9 (22.22%)
occurrences (all)	11	6	2
Lymphocyte count decreased			
subjects affected / exposed	3 / 103 (2.91%)	6 / 44 (13.64%)	0 / 9 (0.00%)
occurrences (all)	3	7	0
Vitamin D decreased			
subjects affected / exposed	3 / 103 (2.91%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	3	1	1
Weight decreased			
subjects affected / exposed	19 / 103 (18.45%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	21	2	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			

subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Cardiac disorders			
Bundle branch block left			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	6 / 103 (5.83%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	6	0	1
Cognitive disorder			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Dizziness			
subjects affected / exposed	12 / 103 (11.65%)	4 / 44 (9.09%)	1 / 9 (11.11%)
occurrences (all)	14	4	2
Disturbance in attention			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	32 / 103 (31.07%)	9 / 44 (20.45%)	6 / 9 (66.67%)
occurrences (all)	35	10	6
Headache			
subjects affected / exposed	6 / 103 (5.83%)	5 / 44 (11.36%)	0 / 9 (0.00%)
occurrences (all)	6	5	0
Hypoaesthesia			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Lethargy			
subjects affected / exposed	0 / 103 (0.00%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Neuropathy peripheral			
subjects affected / exposed	4 / 103 (3.88%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	4	2	1
Peripheral sensory neuropathy			

subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Transient ischaemic attack			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	19 / 103 (18.45%)	10 / 44 (22.73%)	1 / 9 (11.11%)
occurrences (all)	22	10	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Arcus lipoides			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blepharitis			
subjects affected / exposed	8 / 103 (7.77%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences (all)	10	1	0
Cataract			
subjects affected / exposed	6 / 103 (5.83%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences (all)	7	1	0
Corneal neovascularisation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	21 / 103 (20.39%)	7 / 44 (15.91%)	4 / 9 (44.44%)
occurrences (all)	27	7	4
Eye disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye haematoma			

subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Eyelid pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Glaucoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Keratitis			
subjects affected / exposed	4 / 103 (3.88%)	1 / 44 (2.27%)	2 / 9 (22.22%)
occurrences (all)	4	1	2
Lacrimation increased			
subjects affected / exposed	2 / 103 (1.94%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	3	1	1
Meibomian gland dysfunction			
subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Punctate keratitis			
subjects affected / exposed	2 / 103 (1.94%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
Retinal detachment			
subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Subretinal fluid			
subjects affected / exposed	3 / 103 (2.91%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	1
Trichiasis			
subjects affected / exposed	6 / 103 (5.83%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	6	0	0
Trichomegaly			
subjects affected / exposed	4 / 103 (3.88%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	4	0	1
Vision blurred			

subjects affected / exposed	6 / 103 (5.83%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	7	3	1
Visual acuity reduced			
subjects affected / exposed	5 / 103 (4.85%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Visual impairment			
subjects affected / exposed	3 / 103 (2.91%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	5 / 103 (4.85%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	5	4	0
Abdominal pain			
subjects affected / exposed	20 / 103 (19.42%)	11 / 44 (25.00%)	1 / 9 (11.11%)
occurrences (all)	28	12	1
Aphthous ulcer			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Chapped lips			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	36 / 103 (34.95%)	11 / 44 (25.00%)	4 / 9 (44.44%)
occurrences (all)	46	13	4
Diarrhoea			
subjects affected / exposed	53 / 103 (51.46%)	19 / 44 (43.18%)	6 / 9 (66.67%)
occurrences (all)	89	28	8
Dry mouth			
subjects affected / exposed	33 / 103 (32.04%)	13 / 44 (29.55%)	7 / 9 (77.78%)
occurrences (all)	35	13	7
Dyspepsia			
subjects affected / exposed	10 / 103 (9.71%)	1 / 44 (2.27%)	2 / 9 (22.22%)
occurrences (all)	16	1	2
Dysphagia			
subjects affected / exposed	4 / 103 (3.88%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	5	3	0

Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 103 (2.91%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Glossodynia			
subjects affected / exposed	1 / 103 (0.97%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Lip pain			
subjects affected / exposed	0 / 103 (0.00%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	0	4	1
Mouth ulceration			
subjects affected / exposed	2 / 103 (1.94%)	4 / 44 (9.09%)	0 / 9 (0.00%)
occurrences (all)	2	4	0
Nausea			
subjects affected / exposed	28 / 103 (27.18%)	13 / 44 (29.55%)	1 / 9 (11.11%)
occurrences (all)	39	17	1
Oral pain			
subjects affected / exposed	5 / 103 (4.85%)	4 / 44 (9.09%)	1 / 9 (11.11%)
occurrences (all)	5	5	1
Stomatitis			
subjects affected / exposed	48 / 103 (46.60%)	13 / 44 (29.55%)	3 / 9 (33.33%)
occurrences (all)	70	14	3
Tooth disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	19 / 103 (18.45%)	10 / 44 (22.73%)	0 / 9 (0.00%)
occurrences (all)	29	15	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	49 / 103 (47.57%)	16 / 44 (36.36%)	7 / 9 (77.78%)
occurrences (all)	50	16	7
Dry skin			
subjects affected / exposed	21 / 103 (20.39%)	6 / 44 (13.64%)	4 / 9 (44.44%)
occurrences (all)	23	6	5
Erythema			
subjects affected / exposed	3 / 103 (2.91%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	1
Madarosis			
subjects affected / exposed	3 / 103 (2.91%)	3 / 44 (6.82%)	0 / 9 (0.00%)
occurrences (all)	3	3	0
Nail disorder			
subjects affected / exposed	8 / 103 (7.77%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences (all)	9	2	0
Nail discolouration			
subjects affected / exposed	6 / 103 (5.83%)	5 / 44 (11.36%)	1 / 9 (11.11%)
occurrences (all)	6	5	1
Nail toxicity			
subjects affected / exposed	5 / 103 (4.85%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences (all)	6	1	0
Nail dystrophy			
subjects affected / exposed	7 / 103 (6.80%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	8	2	1
Onychalgia			
subjects affected / exposed	4 / 103 (3.88%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences (all)	6	2	0
Onychomadesis			
subjects affected / exposed	6 / 103 (5.83%)	3 / 44 (6.82%)	1 / 9 (11.11%)
occurrences (all)	7	3	1
Onycholysis			
subjects affected / exposed	10 / 103 (9.71%)	6 / 44 (13.64%)	0 / 9 (0.00%)
occurrences (all)	10	7	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	8 / 103 (7.77%)	3 / 44 (6.82%)	1 / 9 (11.11%)
occurrences (all)	10	3	1

Pruritus			
subjects affected / exposed	9 / 103 (8.74%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences (all)	9	2	0
Rash			
subjects affected / exposed	8 / 103 (7.77%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences (all)	8	2	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 103 (3.88%)	5 / 44 (11.36%)	1 / 9 (11.11%)
occurrences (all)	4	6	1
Dysuria			
subjects affected / exposed	4 / 103 (3.88%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	5	1	1
Haematuria			
subjects affected / exposed	8 / 103 (7.77%)	6 / 44 (13.64%)	2 / 9 (22.22%)
occurrences (all)	11	7	2
Proteinuria			
subjects affected / exposed	6 / 103 (5.83%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	6	2	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	19 / 103 (18.45%)	6 / 44 (13.64%)	1 / 9 (11.11%)
occurrences (all)	22	7	1
Back pain			
subjects affected / exposed	18 / 103 (17.48%)	6 / 44 (13.64%)	2 / 9 (22.22%)
occurrences (all)	22	6	2
Muscle fatigue			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	5 / 103 (4.85%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	6	1	1

Muscular weakness			
subjects affected / exposed	9 / 103 (8.74%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	11	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	6 / 103 (5.83%)	1 / 44 (2.27%)	2 / 9 (22.22%)
occurrences (all)	8	1	2
Neck pain			
subjects affected / exposed	5 / 103 (4.85%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	5	2	1
Pain in extremity			
subjects affected / exposed	12 / 103 (11.65%)	4 / 44 (9.09%)	1 / 9 (11.11%)
occurrences (all)	14	5	1
Infections and infestations			
Candida infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Conjunctivitis			
subjects affected / exposed	4 / 103 (3.88%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	5	2	1
Conjunctivitis bacterial			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	2 / 103 (1.94%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Influenza			
subjects affected / exposed	0 / 103 (0.00%)	2 / 44 (4.55%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Oral candidiasis			
subjects affected / exposed	3 / 103 (2.91%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	4	1	1
Oral herpes			

subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	3 / 103 (2.91%)	1 / 44 (2.27%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Urinary tract infection			
subjects affected / exposed	25 / 103 (24.27%)	10 / 44 (22.73%)	1 / 9 (11.11%)
occurrences (all)	31	16	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	32 / 103 (31.07%)	11 / 44 (25.00%)	4 / 9 (44.44%)
occurrences (all)	38	12	4
Dehydration			
subjects affected / exposed	8 / 103 (7.77%)	2 / 44 (4.55%)	1 / 9 (11.11%)
occurrences (all)	12	2	1
Hypercalcaemia			
subjects affected / exposed	11 / 103 (10.68%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	12	2	1
Hypercreatininaemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	3 / 103 (2.91%)	3 / 44 (6.82%)	1 / 9 (11.11%)
occurrences (all)	3	3	1
Hyperkalaemia			
subjects affected / exposed	6 / 103 (5.83%)	4 / 44 (9.09%)	0 / 9 (0.00%)
occurrences (all)	7	7	0
Hyperphosphataemia			
subjects affected / exposed	35 / 103 (33.98%)	13 / 44 (29.55%)	4 / 9 (44.44%)
occurrences (all)	39	15	4
Hypertriglyceridaemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 44 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Hypomagnesaemia			
subjects affected / exposed	3 / 103 (2.91%)	3 / 44 (6.82%)	1 / 9 (11.11%)
occurrences (all)	3	3	1

Hypoalbuminaemia			
subjects affected / exposed	8 / 103 (7.77%)	4 / 44 (9.09%)	0 / 9 (0.00%)
occurrences (all)	8	4	0
Hyponatraemia			
subjects affected / exposed	7 / 103 (6.80%)	6 / 44 (13.64%)	1 / 9 (11.11%)
occurrences (all)	9	10	1
Hypophosphataemia			
subjects affected / exposed	13 / 103 (12.62%)	3 / 44 (6.82%)	1 / 9 (11.11%)
occurrences (all)	20	4	2
Hypouricaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 44 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	4 / 103 (3.88%)	1 / 44 (2.27%)	1 / 9 (11.11%)
occurrences (all)	5	1	1

Non-serious adverse events	Cohort A-CD: FGFR3 mutations or fusions	Other-CD	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	99 / 101 (98.02%)	3 / 3 (100.00%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Orthostatic hypotension			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	32 / 101 (31.68%)	0 / 3 (0.00%)	
occurrences (all)	37	0	
Chills			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Chest pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

Fatigue			
subjects affected / exposed	29 / 101 (28.71%)	1 / 3 (33.33%)	
occurrences (all)	33	1	
Influenza like illness			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Mucosal inflammation			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Oedema peripheral			
subjects affected / exposed	10 / 101 (9.90%)	0 / 3 (0.00%)	
occurrences (all)	10	0	
Pain			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
Pyrexia			
subjects affected / exposed	12 / 101 (11.88%)	0 / 3 (0.00%)	
occurrences (all)	17	0	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 101 (4.95%)	1 / 3 (33.33%)	
occurrences (all)	5	1	
Dyspnoea			
subjects affected / exposed	5 / 101 (4.95%)	1 / 3 (33.33%)	
occurrences (all)	5	1	
Dysphonia			
subjects affected / exposed	4 / 101 (3.96%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Epistaxis			
subjects affected / exposed	14 / 101 (13.86%)	0 / 3 (0.00%)	
occurrences (all)	18	0	
Nasal dryness			

subjects affected / exposed	5 / 101 (4.95%)	0 / 3 (0.00%)	
occurrences (all)	5	0	
Oropharyngeal pain			
subjects affected / exposed	5 / 101 (4.95%)	0 / 3 (0.00%)	
occurrences (all)	5	0	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	5 / 101 (4.95%)	0 / 3 (0.00%)	
occurrences (all)	5	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	9 / 101 (8.91%)	0 / 3 (0.00%)	
occurrences (all)	11	0	
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 101 (6.93%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
Blood creatinine increased			
subjects affected / exposed	20 / 101 (19.80%)	1 / 3 (33.33%)	
occurrences (all)	22	1	
Blood phosphorus increased			
subjects affected / exposed	13 / 101 (12.87%)	1 / 3 (33.33%)	
occurrences (all)	23	1	
Lymphocyte count decreased			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Vitamin D decreased			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Weight decreased			

subjects affected / exposed	12 / 101 (11.88%)	0 / 3 (0.00%)	
occurrences (all)	12	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 101 (1.98%)	1 / 3 (33.33%)	
occurrences (all)	2	1	
Skin abrasion			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Bundle branch block left			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Nervous system disorders			
Ageusia			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Cognitive disorder			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	4 / 101 (3.96%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
Disturbance in attention			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	31 / 101 (30.69%)	1 / 3 (33.33%)	
occurrences (all)	33	1	
Headache			
subjects affected / exposed	5 / 101 (4.95%)	0 / 3 (0.00%)	
occurrences (all)	5	0	
Hypoaesthesia			
subjects affected / exposed	1 / 101 (0.99%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
Lethargy			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	1 / 101 (0.99%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences (all)	5	0	
Transient ischaemic attack			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	18 / 101 (17.82%)	0 / 3 (0.00%)	
occurrences (all)	19	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Eye disorders			
Arcus lipoides			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Blepharitis			
subjects affected / exposed	9 / 101 (8.91%)	1 / 3 (33.33%)	
occurrences (all)	9	1	
Cataract			
subjects affected / exposed	6 / 101 (5.94%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
Corneal neovascularisation			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Detachment of macular retinal pigment epithelium			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Dry eye			

subjects affected / exposed	19 / 101 (18.81%)	1 / 3 (33.33%)	
occurrences (all)	20	1	
Eye disorder			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Eye haematoma			
subjects affected / exposed	1 / 101 (0.99%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
Eye pain			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Eyelid pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Glaucoma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Keratitis			
subjects affected / exposed	5 / 101 (4.95%)	0 / 3 (0.00%)	
occurrences (all)	5	0	
Lacrimation increased			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
Meibomian gland dysfunction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Punctate keratitis			
subjects affected / exposed	7 / 101 (6.93%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
Retinal detachment			
subjects affected / exposed	9 / 101 (8.91%)	1 / 3 (33.33%)	
occurrences (all)	9	1	
Subretinal fluid			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Trichiasis			

subjects affected / exposed	5 / 101 (4.95%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
Trichomegaly			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Vision blurred			
subjects affected / exposed	7 / 101 (6.93%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
Visual acuity reduced			
subjects affected / exposed	10 / 101 (9.90%)	0 / 3 (0.00%)	
occurrences (all)	10	0	
Visual impairment			
subjects affected / exposed	6 / 101 (5.94%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	6 / 101 (5.94%)	0 / 3 (0.00%)	
occurrences (all)	7	0	
Abdominal pain			
subjects affected / exposed	7 / 101 (6.93%)	2 / 3 (66.67%)	
occurrences (all)	9	2	
Aphthous ulcer			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Chapped lips			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	33 / 101 (32.67%)	1 / 3 (33.33%)	
occurrences (all)	35	1	
Diarrhoea			
subjects affected / exposed	34 / 101 (33.66%)	2 / 3 (66.67%)	
occurrences (all)	55	2	
Dry mouth			
subjects affected / exposed	39 / 101 (38.61%)	1 / 3 (33.33%)	
occurrences (all)	39	1	

Dyspepsia			
subjects affected / exposed	7 / 101 (6.93%)	0 / 3 (0.00%)	
occurrences (all)	7	0	
Dysphagia			
subjects affected / exposed	2 / 101 (1.98%)	1 / 3 (33.33%)	
occurrences (all)	2	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	7 / 101 (6.93%)	0 / 3 (0.00%)	
occurrences (all)	7	0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Glossodynia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Lip pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Mouth ulceration			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	18 / 101 (17.82%)	0 / 3 (0.00%)	
occurrences (all)	19	0	
Oral pain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Stomatitis			
subjects affected / exposed	45 / 101 (44.55%)	1 / 3 (33.33%)	
occurrences (all)	56	1	
Tooth disorder			
subjects affected / exposed	1 / 101 (0.99%)	1 / 3 (33.33%)	
occurrences (all)	1	1	

Vomiting			
subjects affected / exposed	12 / 101 (11.88%)	1 / 3 (33.33%)	
occurrences (all)	19	1	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	38 / 101 (37.62%)	1 / 3 (33.33%)	
occurrences (all)	38	1	
Dry skin			
subjects affected / exposed	22 / 101 (21.78%)	2 / 3 (66.67%)	
occurrences (all)	23	2	
Erythema			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
Madarosis			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Nail disorder			
subjects affected / exposed	10 / 101 (9.90%)	0 / 3 (0.00%)	
occurrences (all)	11	0	
Nail discolouration			
subjects affected / exposed	10 / 101 (9.90%)	1 / 3 (33.33%)	
occurrences (all)	10	1	
Nail toxicity			
subjects affected / exposed	7 / 101 (6.93%)	0 / 3 (0.00%)	
occurrences (all)	7	0	
Nail dystrophy			
subjects affected / exposed	6 / 101 (5.94%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
Onychalgia			
subjects affected / exposed	6 / 101 (5.94%)	1 / 3 (33.33%)	
occurrences (all)	6	1	
Onychomadesis			
subjects affected / exposed	8 / 101 (7.92%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
Onycholysis			

subjects affected / exposed	10 / 101 (9.90%)	1 / 3 (33.33%)	
occurrences (all)	10	1	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	28 / 101 (27.72%)	0 / 3 (0.00%)	
occurrences (all)	31	0	
Pruritus			
subjects affected / exposed	4 / 101 (3.96%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Rash			
subjects affected / exposed	8 / 101 (7.92%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 101 (3.96%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Dysuria			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
Haematuria			
subjects affected / exposed	12 / 101 (11.88%)	0 / 3 (0.00%)	
occurrences (all)	15	0	
Proteinuria			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	19 / 101 (18.81%)	0 / 3 (0.00%)	
occurrences (all)	22	0	
Back pain			
subjects affected / exposed	15 / 101 (14.85%)	1 / 3 (33.33%)	
occurrences (all)	15	1	
Muscle fatigue			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	5 / 101 (4.95%)	1 / 3 (33.33%)	
occurrences (all)	5	1	
Muscular weakness			
subjects affected / exposed	4 / 101 (3.96%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Myalgia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Neck pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	15 / 101 (14.85%)	1 / 3 (33.33%)	
occurrences (all)	18	1	
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	6 / 101 (5.94%)	1 / 3 (33.33%)	
occurrences (all)	6	1	
Conjunctivitis bacterial			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Gingivitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	

Oral candidiasis			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
Oral herpes			
subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	8 / 101 (7.92%)	1 / 3 (33.33%)	
occurrences (all)	10	1	
Urinary tract infection			
subjects affected / exposed	10 / 101 (9.90%)	0 / 3 (0.00%)	
occurrences (all)	12	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	29 / 101 (28.71%)	0 / 3 (0.00%)	
occurrences (all)	33	0	
Dehydration			
subjects affected / exposed	3 / 101 (2.97%)	0 / 3 (0.00%)	
occurrences (all)	3	0	
Hypercalcaemia			
subjects affected / exposed	7 / 101 (6.93%)	0 / 3 (0.00%)	
occurrences (all)	8	0	
Hypercreatininaemia			
subjects affected / exposed	6 / 101 (5.94%)	0 / 3 (0.00%)	
occurrences (all)	6	0	
Hyperglycaemia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Hyperkalaemia			
subjects affected / exposed	8 / 101 (7.92%)	0 / 3 (0.00%)	
occurrences (all)	11	0	
Hyperphosphataemia			
subjects affected / exposed	56 / 101 (55.45%)	2 / 3 (66.67%)	
occurrences (all)	95	2	
Hypertriglyceridaemia			

subjects affected / exposed	0 / 101 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	2 / 101 (1.98%)	1 / 3 (33.33%)	
occurrences (all)	2	1	
Hypoalbuminaemia			
subjects affected / exposed	2 / 101 (1.98%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Hyponatraemia			
subjects affected / exposed	9 / 101 (8.91%)	0 / 3 (0.00%)	
occurrences (all)	12	0	
Hypophosphataemia			
subjects affected / exposed	4 / 101 (3.96%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Hypouricaemia			
subjects affected / exposed	0 / 101 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Vitamin D deficiency			
subjects affected / exposed	2 / 101 (1.98%)	1 / 3 (33.33%)	
occurrences (all)	2	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 September 2016	The primary purpose of this amendment was to update language based on Regulatory Agencies comments. Updates included but were not limited to clarification of inclusion and exclusion criteria, the addition of an independent data monitoring committee, and the removal of language indicating the futility analysis was nonbinding.
17 November 2016	The primary purpose of this amendment was to change the parameters associated with an exclusion criterion.
02 February 2017	The primary purpose of this amendment was to revise language in the Protocol to provide flexibility for enrollment and to update previous clinical experience data to align with the Investigator's Brochure (version 3).
29 November 2017	The primary purpose of this amendment was to refine the participant population, to divide the study population into cohorts, and to provide a list of possible eligible alterations.
18 June 2018	The main purpose of this amendment was to add language to allow for continuous administration of pemigatinib. Updated clinical data were added to support continuous administration. Additional language was added for Japanese participants. Other modifications were made based on new preclinical and/or clinical data.
20 November 2018	The primary purpose of this amendment was to include up-titration language, to expand translational sciences assessments, and to include additional safety data.
09 March 2020	The primary purpose of this amendment was to incorporate previous administrative changes and include updated language for comprehensive eye examination, per Food and Drug Administration (FDA) feedback.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported