



Clinical trial results: A Phase 2 Study of Futibatinib in Patients With Specific FGFR Aberrations

Summary

EudraCT number	2019-004084-49
Trial protocol	SE GB NL FR BE PT IT
Global end of trial date	11 November 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	TAS-120-202
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04189445
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Taiho Oncology, Inc.
Sponsor organisation address	101 Carnegie Center, Suite 101, Princeton, New Jersey, United States, 08540
Public contact	Senior Study Manager, Taiho Oncology, Inc., +1 844-878-2446, medicalinformation@taihooncology.com
Scientific contact	Senior Study Manager, Taiho Oncology, Inc., +1 844-878-2446, medicalinformation@taihooncology.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	11 November 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Cohorts A and B: The primary objective was to evaluate the objective response rate (ORR) in subjects with solid tumors harboring FGFR rearrangements or gastric cancer (including GEJ cancer) harboring FGFR2 amplifications based on independent central review of radiologic images (IRC).

Cohort C: The overall objective of Cohort C was to assess the clinical activity of futibatinib as monotherapy in the treatment of subjects with myeloid/lymphoid neoplasms (MLN) harboring FGFR1 rearrangements.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 August 2020
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	Japan: 26
Country: Number of subjects enrolled	Korea, Republic of: 27
Country: Number of subjects enrolled	France: 15
Country: Number of subjects enrolled	United States: 12
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Türkiye: 4
Country: Number of subjects enrolled	Singapore: 6
Country: Number of subjects enrolled	Sweden: 2
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Germany: 1
Worldwide total number of subjects	115
EEA total number of subjects	34

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)	71
From 65 to 84 years	44
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study from 05 August 2020 to 11 November 2024.

Pre-assignment

Screening details:

A total of 115 subjects were enrolled in Cohort A and Cohort B to receive futibatinib. As no subjects were enrolled in Cohort C, data was not collected for any of the pre-specified primary and secondary endpoints for Cohort C and hence not included in the results.

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	Futibatinib (Cohort A)

Arm description:

Subjects with advanced or metastatic solid tumors harboring fibroblast growth factor receptor (FGFR)1-4 rearrangements received futibatinib 20 milligrams (mg), oral tablets, once a day on a continuous 28-day cycle up to a maximum of 841 days.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Futibatinib at an oral dose of 20 mg, administered once a day, on a continuous 28-day cycle.

Arm title	Futibatinib (Cohort B)
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Arm description:

Subjects with advanced or metastatic solid gastric or gastro-esophageal junction (GEJ) cancer harboring FGFR2 amplification received futibatinib 20 mg, oral tablets, once a day on a continuous 28-day cycle up to a maximum of 297 days.

Arm type	Experimental
Investigational medicinal product name	Futibatinib
Investigational medicinal product code	TAS-120
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Futibatinib at an oral dose of 20 mg, administered once a day, on a continuous 28-day cycle.

Number of subjects in period 1	Futibatinib (Cohort A)	Futibatinib (Cohort B)
Started	87	28
Completed	0	0
Not completed	87	28
Consent withdrawn by subject	8	1
Death	54	24
Study Terminated by Sponsor	25	3

Baseline characteristics

Reporting groups

Reporting group title	Futibatinib (Cohort A)
Reporting group description:	
Subjects with advanced or metastatic solid tumors harboring fibroblast growth factor receptor (FGFR)1-4 rearrangements received futibatinib 20 milligrams (mg), oral tablets, once a day on a continuous 28-day cycle up to a maximum of 841 days.	
Reporting group title	Futibatinib (Cohort B)
Reporting group description:	
Subjects with advanced or metastatic solid gastric or gastro-esophageal junction (GEJ) cancer harboring FGFR2 amplification received futibatinib 20 mg, oral tablets, once a day on a continuous 28-day cycle up to a maximum of 297 days.	

Reporting group values	Futibatinib (Cohort A)	Futibatinib (Cohort B)	Total
Number of subjects	87	28	115
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	53	18	71
From 65-84 years	34	10	44
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	60.0	55.6	
standard deviation	± 12.47	± 13.77	-
Gender categorical			
Units: Subjects			
Female	47	16	63
Male	40	12	52
Race			
Units: Subjects			
Caucasian/White	29	3	32
Black or African American	1	0	1
Asian	36	24	60
Other	1	0	1
Unknown	20	1	21
Ethnicity			
Units: Subjects			
Hispanic or Latino	3	1	4
Not Hispanic or Latino	62	26	88
Unknown	22	1	23

End points

End points reporting groups

Reporting group title	Futibatinib (Cohort A)
Reporting group description: Subjects with advanced or metastatic solid tumors harboring fibroblast growth factor receptor (FGFR)1-4 rearrangements received futibatinib 20 milligrams (mg), oral tablets, once a day on a continuous 28-day cycle up to a maximum of 841 days.	
Reporting group title	Futibatinib (Cohort B)
Reporting group description: Subjects with advanced or metastatic solid gastric or gastro-esophageal junction (GEJ) cancer harboring FGFR2 amplification received futibatinib 20 mg, oral tablets, once a day on a continuous 28-day cycle up to a maximum of 297 days.	

Primary: Objective Response Rate (ORR) Based on Independent Central Review (IRC)

End point title	Objective Response Rate (ORR) Based on Independent Central Review (IRC) ^[1]
End point description: ORR was defined as the percentage of subjects experiencing a best overall response of partial response (PR) or complete response (CR) (per Response Evaluation Criteria in Solid Tumors, RECIST version 1.1), based on IRC of radiological images. CR was defined as disappearance of all target lesions. Any pathological lymph node must have reduction in short axis to <10 millimeters (mm). PR was defined as at least a 30% decrease in the sum of diameters of the target lesions, taking as a reference the baseline sum diameters. ORR was calculated based on the best overall response recorded from the start of treatment until progressive disease or start of subsequent new anticancer treatment. Percentages were rounded off to the nearest single decimal place. All treated population included all subjects who received at least 1 dose of study drug.	
End point type	Primary
End point timeframe: At the end of every 2 cycles until disease progression (Up to 31 months)	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Only descriptive statistics is provided for this end point.	

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	28		
Units: percentage of subjects				
number (confidence interval 95%)	6.9 (2.6 to 14.4)	17.9 (6.1 to 36.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: ORR Based on Investigator Assessment

End point title	ORR Based on Investigator Assessment
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End point description:

ORR was defined as the percentage of subjects experiencing a best overall response of PR or CR (per RECIST 1.1), based on investigator assessment. CR was defined as disappearance of all target lesions. Any pathological lymph node must have reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of the target lesions, taking as a reference the baseline sum diameters. ORR was calculated based on the best overall response recorded from the start of treatment until progressive disease or start of subsequent new anticancer treatment. Percentages were rounded off to the nearest single decimal place. All treated population included all subjects who received at least 1 dose of study drug.

End point type	Secondary
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End point timeframe:

At the end of every 2 cycles until disease progression (Up to 31 months)

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	28		
Units: percentage of subjects				
number (confidence interval 95%)	9.2 (4.1 to 17.3)	10.7 (2.3 to 28.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) Based on IRC

End point title	Duration of Response (DOR) Based on IRC
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End point description:

DOR was defined as the time from the first documentation of response (CR or PR in based on IRC) to the first documentation of objective tumor progression or death due to any cause, whichever occurs first. CR was defined as disappearance of all target lesions. Any pathological lymph node must have reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of the target lesions, taking as a reference the baseline sum diameters. DOR was estimated using the Kaplan-Meier method. All responders' population included all subjects who received at least 1 dose of study drug and had a response. Subjects analysed are the number of subjects with events. '9999' signifies that upper limit of 95% confidence interval (CI) was not estimable due to insufficient events.

End point type	Secondary
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End point timeframe:

At the end of every 2 cycles until disease progression (Up to 31 months)

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	5		
Units: months				
median (confidence interval 95%)	5.6 (3.5 to 9999)	3.9 (2.1 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: DOR Based on Investigator Assessment

End point title	DOR Based on Investigator Assessment
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End point description:

DOR was defined as the time from the first documentation of response (CR or PR in based on Investigator Assessment) to the first documentation of objective tumor progression or death due to any cause, whichever occurs first. CR was defined as disappearance of all target lesions. Any pathological lymph node must have reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of the target lesions, taking as a reference the baseline sum diameters. DOR was estimated using the Kaplan–Meier method. All responders' population included all subjects who received at least 1 dose of study drug and had a response. Subjects analysed are the number of subjects with events. '9999' signifies that the upper limit of 95% CI was not estimable due to insufficient events.

End point type	Secondary
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End point timeframe:

At the end of every 2 cycles until disease progression (Up to 31 months)

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	3		
Units: months				
median (confidence interval 95%)	5.6 (3.0 to 9999)	5.6 (2.0 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression- Free Survival (PFS) Based on IRC

End point title	Progression- Free Survival (PFS) Based on IRC
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End point description:

PFS was defined as the time from first dose of the study therapy to the date of death (any cause) or disease progression (based on IRC), whichever occurs first. The PFS was analysed using a Kaplan-Meier method, with PFS time being censored on the date of the last disease assessment. The 95% CI for median PFS was provided using the Kaplan-Meier procedure. All treated population included all subjects who received at least 1 dose of study drug. Subjects analysed are the number of subjects with reported disease progression or death.

End point type	Secondary
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End point timeframe:

At the end of every 2 cycles until disease progression (Up to 31 months)

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	23		
Units: months				
median (confidence interval 95%)	1.9 (1.8 to 3.5)	2.9 (1.8 to 3.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: PFS Based on Investigator Review

End point title	PFS Based on Investigator Review
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End point description:

PFS was defined as the time from first dose of the study therapy to the date of death (any cause) or disease progression (based on Investigator Review), whichever occurs first. The PFS was analysed using a Kaplan Meier method, with PFS time being censored on the date of the last disease assessment. The 95% CI for median PFS was provided using the Kaplan-Meier procedure. All treated population included all subjects who received at least 1 dose of study drug. Subjects analysed are the number of subjects with reported disease progression or death.

End point type	Secondary
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End point timeframe:

At the end of every 2 cycles until disease progression (Up to 31 months)

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	25		
Units: months				
median (confidence interval 95%)	3.3 (1.9 to 3.8)	3.3 (2.1 to 3.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

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

OS was defined as the time from the date of first dose to the death date. Subjects without a documented death date were censored on the last date they were known to be alive. The OS was presented using a Kaplan-Meier estimate. The 95% CI for median OS was provided using the Kaplan-Meier procedure. All treated population included all subjects who received at least 1 dose of study drug. Subjects analysed are the number of subjects with reported death.

End point type	Secondary
End point timeframe:	
Up to 31 months	

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	24		
Units: months				
median (confidence interval 95%)	11.1 (7.3 to 15.6)	5.9 (3.9 to 8.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR) Based on IRC

End point title	Disease Control Rate (DCR) Based on IRC
End point description:	
DCR was defined as the percentage of subjects experiencing a best overall response of stable disease (SD), PR, or CR (per RECIST 1.1), based on IRC. SD was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD), referencing the smallest sum diameters while on study. PD was defined as at least a 20% increase in the sum of target lesion diameters from the smallest on study (including baseline), with an absolute increase of ≥ 5 mm, or the appearance of new lesions. CR was defined as disappearance of all target lesions. Any pathological lymph node must have reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of the target lesions, taking as a reference the baseline sum diameters. Percentages were rounded off to the nearest single decimal place. All treated population included all subjects who received at least 1 dose of study drug.	
End point type	Secondary
End point timeframe:	
At the end of every 2 cycles until disease progression (Up to 31 months)	

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	28		
Units: percentage of subjects				
number (confidence interval 95%)	37.9 (27.7 to 49.0)	50.0 (30.6 to 69.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: DCR Based on Investigator Review

End point title	DCR Based on Investigator Review
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End point description:

DCR was defined as the percentage of subjects experiencing a best overall response of SD, PR, or CR (per RECIST 1.1), based on IRC. SD was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD), referencing the smallest sum diameters while on study. PD was defined as at least a 20% increase in the sum of target lesion diameters from the smallest on study (including baseline), with an absolute increase of ≥ 5 mm, or the appearance of new lesions. CR was defined as disappearance of all target lesions. Any pathological lymph node must have reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of the target lesions, taking as a reference the baseline sum diameters. Percentages were rounded off to the nearest single decimal place. All treated population included all subjects who received at least 1 dose of study drug.

End point type	Secondary
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End point timeframe:

At the end of every 2 cycles until disease progression (Up to 31 months)

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	28		
Units: percentage of subjects				
number (confidence interval 95%)	52.9 (41.9 to 63.7)	64.3 (44.1 to 81.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs)
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End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a clinical study subject and does not necessarily have a causal relationship with the study drug. A treatment-emergent AE (TEAE) is defined as an AE that is starting or worsening at the time of or after the first dose of study drug administration and within 30 days after the last dose of study drug and does not necessarily have a causal relationship to the use of the study drug. All treated population included all subjects who received at least 1 dose of study drug.

End point type	Secondary
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End point timeframe:

From the first dose of study drug up to 30 days after the last dose (Up to 31 months)

End point values	Futibatinib (Cohort A)	Futibatinib (Cohort B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	28		
Units: Subjects	87	27		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose of study drug up to 30 days after the last dose (Up to 31 months)

Adverse event reporting additional description:

All treated population included all subjects who received at least 1 dose of study drug. No subjects were enrolled in Cohort C, hence no data was collected.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	Futibatinib (Cohort A)
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Reporting group description:

Subjects with advanced or metastatic solid tumors harboring fibroblast growth factor receptor (FGFR)1-4 rearrangements received futibatinib 20 milligrams (mg), oral tablets, once a day on a continuous 28-day cycle up to a maximum of 841 days.

Reporting group title	Futibatinib (Cohort B)
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Reporting group description:

Subjects with advanced or metastatic solid gastric or gastro-esophageal junction (GEJ) cancer harboring FGFR2 amplification received futibatinib 20 mg, oral tablets, once a day on a continuous 28-day cycle up to a maximum of 297 days.

Serious adverse events	Futibatinib (Cohort A)	Futibatinib (Cohort B)	
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 87 (26.44%)	6 / 28 (21.43%)	
number of deaths (all causes)	54	24	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant pleural effusion			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	2 / 87 (2.30%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	5 / 87 (5.75%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

Blood lactic acid increased subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical condition abnormal subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Spinal compression fracture subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Eyelid ptosis subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ascites subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (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	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 87 (0.00%)	2 / 28 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemobilia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

Calculus urinary			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Rhabdomyolysis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 87 (2.30%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 87 (2.30%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Futibatinib (Cohort A)	Futibatinib (Cohort B)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	86 / 87 (98.85%)	27 / 28 (96.43%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	2 / 87 (2.30%)	1 / 28 (3.57%)	
occurrences (all)	2	1	
Tumour pain			
subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Embolism			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
General disorders and administration site conditions			

Fatigue		
subjects affected / exposed	15 / 87 (17.24%)	4 / 28 (14.29%)
occurrences (all)	15	4
Asthenia		
subjects affected / exposed	13 / 87 (14.94%)	2 / 28 (7.14%)
occurrences (all)	13	2
Pyrexia		
subjects affected / exposed	6 / 87 (6.90%)	0 / 28 (0.00%)
occurrences (all)	6	0
Oedema peripheral		
subjects affected / exposed	4 / 87 (4.60%)	1 / 28 (3.57%)
occurrences (all)	4	1
Mucosal inflammation		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Pain		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Chest discomfort		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Effusion		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Gait disturbance		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Malaise		
subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)
occurrences (all)	1	1
Peripheral swelling		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Secretion discharge		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0

Tenderness subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Thirst subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Reproductive system and breast disorders Pelvic pain subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	1 / 28 (3.57%) 1	
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	6 / 87 (6.90%) 6	3 / 28 (10.71%) 3	
Cough subjects affected / exposed occurrences (all)	5 / 87 (5.75%) 6	1 / 28 (3.57%) 1	
Epistaxis subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 2	1 / 28 (3.57%) 1	
Productive cough subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 2	0 / 28 (0.00%) 0	
Haemoptysis subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Hiccups subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Pneumonitis subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Hypoxia			

subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	1 / 28 (3.57%) 1	
Pleural effusion subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	1 / 28 (3.57%) 1	
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 2	0 / 28 (0.00%) 0	
Depressed mood subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Disorientation subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Insomnia subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	2 / 28 (7.14%) 2	
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	19 / 87 (21.84%) 30	6 / 28 (21.43%) 10	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	15 / 87 (17.24%) 27	7 / 28 (25.00%) 10	
Blood creatinine increased subjects affected / exposed occurrences (all)	11 / 87 (12.64%) 13	3 / 28 (10.71%) 4	
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	6 / 87 (6.90%) 7	1 / 28 (3.57%) 2	
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	5 / 87 (5.75%) 5	0 / 28 (0.00%) 0	
Blood alkaline phosphatase increased			

subjects affected / exposed	4 / 87 (4.60%)	2 / 28 (7.14%)
occurrences (all)	6	5
Blood phosphorus increased		
subjects affected / exposed	4 / 87 (4.60%)	0 / 28 (0.00%)
occurrences (all)	4	0
Lymphocyte count decreased		
subjects affected / exposed	3 / 87 (3.45%)	1 / 28 (3.57%)
occurrences (all)	5	1
Weight decreased		
subjects affected / exposed	3 / 87 (3.45%)	2 / 28 (7.14%)
occurrences (all)	3	2
Activated partial thromboplastin time prolonged		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood albumin abnormal		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood calcium increased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood creatine increased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood fibrinogen increased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood magnesium decreased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood thyroid stimulating hormone increased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood triglycerides increased		

subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood urine present		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Creatinine renal clearance decreased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Electrocardiogram QT prolonged		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Heart rate abnormal		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
International normalised ratio increased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Myoglobin blood increased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Neutrophil count decreased		
subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)
occurrences (all)	1	1
Platelet count decreased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
SARS-CoV-2 test positive		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
White blood cell count decreased		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Blood bilirubin increased		
subjects affected / exposed	0 / 87 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	2

Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	1 / 28 (3.57%) 2	
Injury, poisoning and procedural complications			
Fall subjects affected / exposed occurrences (all)	3 / 87 (3.45%) 3	0 / 28 (0.00%) 0	
Injury subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Neurological procedural complication subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Rib fracture subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Congenital, familial and genetic disorders			
Congenital dyskeratosis subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 0	0 / 28 (0.00%) 0	
Cardiac disorders			
Sinus bradycardia subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 2	0 / 28 (0.00%) 0	
Cardiac disorder subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 0	0 / 28 (0.00%) 0	
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 0	0 / 28 (0.00%) 0	
Tachycardia subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 0	0 / 28 (0.00%) 0	
Nervous system disorders			
Dysgeusia			

subjects affected / exposed	11 / 87 (12.64%)	1 / 28 (3.57%)	
occurrences (all)	11	1	
Headache			
subjects affected / exposed	5 / 87 (5.75%)	2 / 28 (7.14%)	
occurrences (all)	5	2	
Paraesthesia			
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Ataxia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Encephalopathy			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Neuralgia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Peripheral motor neuropathy			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Somnolence			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	16 / 87 (18.39%)	3 / 28 (10.71%)	
occurrences (all)	16	3	

Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Ear and labyrinth disorders			
Deafness subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Ear pain subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Tinnitus subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	1 / 28 (3.57%) 1	
Eye disorders			
Keratitis subjects affected / exposed occurrences (all)	4 / 87 (4.60%) 5	2 / 28 (7.14%) 2	
Dry eye subjects affected / exposed occurrences (all)	3 / 87 (3.45%) 3	2 / 28 (7.14%) 2	
Vision blurred subjects affected / exposed occurrences (all)	3 / 87 (3.45%) 3	1 / 28 (3.57%) 1	
Cataract subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 2	1 / 28 (3.57%) 1	
Lacrimation increased subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 2	1 / 28 (3.57%) 1	
Diplopia subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Eye discharge			

subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)	
occurrences (all)	1	2	
Eye disorder			
subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Ocular hyperaemia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Trichiasis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Xerophthalmia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Retinal disorder			
subjects affected / exposed	0 / 87 (0.00%)	2 / 28 (7.14%)	
occurrences (all)	0	2	
Blepharitis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Eye pain			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Meibomian gland dysfunction			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Serous retinal detachment			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	3	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	36 / 87 (41.38%)	6 / 28 (21.43%)	
occurrences (all)	45	6	
Constipation			
subjects affected / exposed	28 / 87 (32.18%)	3 / 28 (10.71%)	
occurrences (all)	30	3	

Dry mouth		
subjects affected / exposed	20 / 87 (22.99%)	1 / 28 (3.57%)
occurrences (all)	20	1
Abdominal pain		
subjects affected / exposed	14 / 87 (16.09%)	2 / 28 (7.14%)
occurrences (all)	14	4
Stomatitis		
subjects affected / exposed	12 / 87 (13.79%)	2 / 28 (7.14%)
occurrences (all)	12	2
Nausea		
subjects affected / exposed	8 / 87 (9.20%)	6 / 28 (21.43%)
occurrences (all)	10	7
Vomiting		
subjects affected / exposed	8 / 87 (9.20%)	4 / 28 (14.29%)
occurrences (all)	9	4
Gastrooesophageal reflux disease		
subjects affected / exposed	5 / 87 (5.75%)	1 / 28 (3.57%)
occurrences (all)	5	1
Dyspepsia		
subjects affected / exposed	3 / 87 (3.45%)	0 / 28 (0.00%)
occurrences (all)	3	0
Gastritis		
subjects affected / exposed	3 / 87 (3.45%)	0 / 28 (0.00%)
occurrences (all)	3	0
Abdominal pain upper		
subjects affected / exposed	2 / 87 (2.30%)	1 / 28 (3.57%)
occurrences (all)	3	1
Oral pain		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Abdominal discomfort		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Anal inflammation		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0

Angular cheilitis		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Ascites		
subjects affected / exposed	1 / 87 (1.15%)	2 / 28 (7.14%)
occurrences (all)	1	2
Glossitis		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Irritable bowel syndrome		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Lip swelling		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Mouth haemorrhage		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Odynophagia		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Oral dysaesthesia		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Small intestinal obstruction		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Dysphagia		
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	1
Gastric stenosis		
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	1

Toothache subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	1 / 28 (3.57%) 1	
Hepatobiliary disorders			
Cholestasis subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 2	0 / 28 (0.00%) 0	
Hepatic function abnormal subjects affected / exposed occurrences (all)	2 / 87 (2.30%) 3	1 / 28 (3.57%) 1	
Hepatic cytolysis subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Hepatic pain subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Jaundice cholestatic subjects affected / exposed occurrences (all)	1 / 87 (1.15%) 1	0 / 28 (0.00%) 0	
Liver disorder subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	2 / 28 (7.14%) 2	
Skin and subcutaneous tissue disorders			
Dry skin subjects affected / exposed occurrences (all)	10 / 87 (11.49%) 10	0 / 28 (0.00%) 0	
Onychomadesis subjects affected / exposed occurrences (all)	7 / 87 (8.05%) 7	1 / 28 (3.57%) 1	
Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all)	6 / 87 (6.90%) 6	1 / 28 (3.57%) 1	
Alopecia subjects affected / exposed occurrences (all)	4 / 87 (4.60%) 4	1 / 28 (3.57%) 1	
Nail disorder			

subjects affected / exposed	4 / 87 (4.60%)	1 / 28 (3.57%)
occurrences (all)	4	1
Onycholysis		
subjects affected / exposed	4 / 87 (4.60%)	0 / 28 (0.00%)
occurrences (all)	4	0
Nail discolouration		
subjects affected / exposed	3 / 87 (3.45%)	0 / 28 (0.00%)
occurrences (all)	3	0
Dermatitis		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Eczema		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Nail dystrophy		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Pruritus		
subjects affected / exposed	2 / 87 (2.30%)	1 / 28 (3.57%)
occurrences (all)	2	1
Rash		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Rash maculo-papular		
subjects affected / exposed	2 / 87 (2.30%)	1 / 28 (3.57%)
occurrences (all)	2	1
Hair texture abnormal		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Hyperkeratosis		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Hypertrichosis		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Palmoplantar keratoderma		

subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Purpura			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Skin disorder			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Skin ulcer			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Acute kidney injury			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Pyelocaliectasis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Renal colic			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Urinary tract obstruction			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Hydronephrosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	8 / 87 (9.20%)	1 / 28 (3.57%)	
occurrences (all)	8	1	
Arthralgia			

subjects affected / exposed	7 / 87 (8.05%)	2 / 28 (7.14%)
occurrences (all)	7	2
Back pain		
subjects affected / exposed	6 / 87 (6.90%)	0 / 28 (0.00%)
occurrences (all)	6	0
Muscle spasms		
subjects affected / exposed	3 / 87 (3.45%)	0 / 28 (0.00%)
occurrences (all)	3	0
Pain in extremity		
subjects affected / exposed	3 / 87 (3.45%)	0 / 28 (0.00%)
occurrences (all)	3	0
Muscle tightness		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Musculoskeletal chest pain		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Arthritis		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Muscular weakness		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Musculoskeletal stiffness		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Myopathy		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Pain in jaw		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Bone pain		
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	1
Musculoskeletal pain		

subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	1 / 28 (3.57%) 1	
Infections and infestations			
Paronychia			
subjects affected / exposed	7 / 87 (8.05%)	0 / 28 (0.00%)	
occurrences (all)	8	0	
Urinary tract infection			
subjects affected / exposed	7 / 87 (8.05%)	0 / 28 (0.00%)	
occurrences (all)	8	0	
Conjunctivitis			
subjects affected / exposed	4 / 87 (4.60%)	3 / 28 (10.71%)	
occurrences (all)	4	3	
COVID-19			
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Gingivitis			
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Abscess limb			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Cystitis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Dermatophytosis of nail			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Ear infection			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Onychomycosis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	

Oral candidiasis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Oral herpes			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Otitis externa			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Tinea pedis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Tooth infection			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Vaginal infection			
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Herpes zoster			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Urosepsis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Hyperphosphataemia			
subjects affected / exposed	70 / 87 (80.46%)	25 / 28 (89.29%)	
occurrences (all)	97	34	
Decreased appetite			

subjects affected / exposed	18 / 87 (20.69%)	10 / 28 (35.71%)
occurrences (all)	18	11
Hypercalcaemia		
subjects affected / exposed	4 / 87 (4.60%)	2 / 28 (7.14%)
occurrences (all)	6	5
Hyponatraemia		
subjects affected / exposed	4 / 87 (4.60%)	3 / 28 (10.71%)
occurrences (all)	5	4
Hypomagnesaemia		
subjects affected / exposed	3 / 87 (3.45%)	2 / 28 (7.14%)
occurrences (all)	3	3
Dehydration		
subjects affected / exposed	2 / 87 (2.30%)	0 / 28 (0.00%)
occurrences (all)	2	0
Hypokalaemia		
subjects affected / exposed	2 / 87 (2.30%)	2 / 28 (7.14%)
occurrences (all)	2	2
Hypertriglyceridaemia		
subjects affected / exposed	1 / 87 (1.15%)	1 / 28 (3.57%)
occurrences (all)	1	4
Hypovolaemia		
subjects affected / exposed	1 / 87 (1.15%)	0 / 28 (0.00%)
occurrences (all)	1	0
Hypoalbuminaemia		
subjects affected / exposed	0 / 87 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	3
Hypophosphataemia		
subjects affected / exposed	0 / 87 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	2
Hyperglycaemia		
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	1
Hyperkalaemia		
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	1
Hyperuricaemia		

subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Hypoglycaemia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 December 2021	The following changes were made as per Amendment 2: 1. Increased Cohort A sample size from 60 to 100 patients; total study population updated from 115 to 155. 2. Modified benefit/risk sections and COVID-19 procedures; incorporated regulatory feedback. 3. Terminology updated throughout: "Trial" to "study" (except in "clinical trial"); "Subjects"/"participants" to "patients" (except "healthy subjects"); "Study therapy/treatment/medication" to "study drug"; "Tumor assessment" to "response assessment"; "Signing of the ICF" to "documented informed consent" 4. DOR specified as "Key Secondary" and other endpoints as "Additional Secondary" in Cohorts A & B. 5. PopPK statement revised to reflect pooled analysis and exposure-response assessment. 6. Inclusion criteria updated: "Gastric or GEJ cancer" changed to "adenocarcinoma" 7. Interim analysis section revised to allow additional regulatory analyses. 8. Added "per RECIST 1.1" to objective response rate; updated response and disease control definitions. 9. Added new section: "Population PK and Exposure-Response Analyses."

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The Sponsor made a strategic decision to terminate the study considering enrollment challenges for some of the cohorts in the trial.

Notes: