



Clinical trial results:

A Phase 2 Study of TAS-120 in Metastatic Breast Cancers Harboring Fibroblast Growth Factor Receptor (FGFR) Amplifications

Summary

EudraCT number	2019-001164-30
Trial protocol	GB PT ES IT
Global end of trial date	06 September 2023

Results information

Result version number	v1 (current)
This version publication date	14 November 2025
First version publication date	14 November 2025

Trial information

Trial identification

Sponsor protocol code	TAS-120-201
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04024436
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Taiho Oncology, Inc.
Sponsor organisation address	101 Carnegie Center, Suite 101, Princeton, United States, NJ 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	06 September 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 September 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the anti-tumor activity of TAS-120 as monotherapy or in combination with fulvestrant in the treatment of subjects with metastatic breast cancer harboring fibroblast growth factor receptor (FGFR) amplifications.

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	28 January 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Portugal: 5
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	United States: 35
Worldwide total number of subjects	64
EEA total number of subjects	18

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)	52
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study from 28 January 2020 to 06 September 2023.

Pre-assignment

Screening details:

A total of 64 subjects were enrolled in either Cohorts 1, 2 or 3 to receive futibatinib or to Cohort 4 to receive futibatinib plus fulvestrant.

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 1)

Arm description:

Subjects with advanced or metastatic hormone receptor – positive (HR+), human epidermal growth factor receptor 2 - negative (HER2-) breast cancer, harboring fibroblast growth factor receptor 2 (FGFR2) gene amplification, with measurable disease received futibatinib, 20 milligrams (mg), oral tablets, once daily for a continuous 28-day cycle up to maximum of 244 days.

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

Dosage and administration details:

Futibatinib administered as 20mg oral tablets once daily for a continuous 28-day cycle.

Arm title	Futibatinib (Cohort 2)
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Arm description:

Subjects with advanced or metastatic triple negative breast cancer (TNBC), harboring FGFR2 gene amplification, with measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 1066 days.

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

Dosage and administration details:

Futibatinib administered as 20mg oral tablets once daily for a continuous 28-day cycle.

Arm title	Futibatinib (Cohort 3)
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Arm description:

Subjects with advanced or metastatic HR+, HER2- or TNBC, breast cancer harboring FGFR2 gene amplification, with non-measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 252 days.

Arm type	Experimental
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Investigational medicinal product name	Futibatinib
Investigational medicinal product code	
Other name	TAS-120
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Futibatinib administered as 20mg oral tablets once daily for a continuous 28-day cycle.	
Arm title	Futibatinib Plus Fulvestrant (Cohort 4)

Arm description:

Subjects with advanced or metastatic HR+ HER2- breast cancer, harboring FGFR1 gene amplification, with measurable disease, received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 645 days. They also received intramuscular (IM) fulvestrant 500 mg on Days 1 and 15 of Cycle 1 and Day 1 of every subsequent cycle up to maximum of 618 days.

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

Dosage and administration details:

Futibatinib administered as 20mg oral tablets once daily for a continuous 28-day cycle.

Investigational medicinal product name	Fulvestrant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Fulvestrant administered as 500 mg IM injection on Days 1 and 15 of Cycle 1, then Day 1 of every subsequent 28-day cycle.

Number of subjects in period 1	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)
Started	17	21	4
Completed	0	0	0
Not completed	17	21	4
Death	10	14	2
Reason Not Specified	-	1	-
Withdrawal of consent	2	-	-
Study termination by sponsor	4	6	2
Loss to follow up	1	-	-

Number of subjects in period 1	Futibatinib Plus Fulvestrant (Cohort 4)
Started	22
Completed	0
Not completed	22
Death	7

Reason Not Specified	2
Withdrawal of consent	1
Study termination by sponsor	11
Loss to follow up	1

Baseline characteristics

Reporting groups

Reporting group title	Futibatinib (Cohort 1)
Reporting group description:	
Subjects with advanced or metastatic hormone receptor – positive (HR+), human epidermal growth factor receptor 2 - negative (HER2-) breast cancer, harboring fibroblast growth factor receptor 2 (FGFR2) gene amplification, with measurable disease received futibatinib, 20 milligrams (mg), oral tablets, once daily for a continuous 28-day cycle up to maximum of 244 days.	
Reporting group title	Futibatinib (Cohort 2)
Reporting group description:	
Subjects with advanced or metastatic triple negative breast cancer (TNBC), harboring FGFR2 gene amplification, with measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 1066 days.	
Reporting group title	Futibatinib (Cohort 3)
Reporting group description:	
Subjects with advanced or metastatic HR+, HER2- or TNBC, breast cancer harboring FGFR2 gene amplification, with non-measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 252 days.	
Reporting group title	Futibatinib Plus Fulvestrant (Cohort 4)
Reporting group description:	
Subjects with advanced or metastatic HR+ HER2- breast cancer, harboring FGFR1 gene amplification, with measurable disease, received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 645 days. They also received intramuscular (IM) fulvestrant 500 mg on Days 1 and 15 of Cycle 1 and Day 1 of every subsequent cycle up to maximum of 618 days.	

Reporting group values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)
Number of subjects	17	21	4
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	59.8	51.4	60.8
standard deviation	± 11.42	± 14.50	± 5.74
Gender categorical			
Units: Subjects			
Female	17	21	4
Male	0	0	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	1	1	0
Not Hispanic or Latino	15	15	4
Unknown or Not Reported	1	5	0
Race			
Units: Subjects			
Caucasian/White	14	12	4
Black or African American	2	1	0
Asian	1	0	0
American Indian or Alaskan Native	0	0	0

Native Hawaiian or Other Pacific Islander	0	1	0
Unknown	0	7	0

Reporting group values	Futibatinib Plus Fulvestrant (Cohort 4)	Total	
Number of subjects	22	64	
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	52.7 ± 12.68	-	
Gender categorical Units: Subjects			
Female	22	64	
Male	0	0	
Ethnicity Units: Subjects			
Hispanic or Latino	2	4	
Not Hispanic or Latino	13	47	
Unknown or Not Reported	7	13	
Race Units: Subjects			
Caucasian/White	16	46	
Black or African American	1	4	
Asian	1	2	
American Indian or Alaskan Native	0	0	
Native Hawaiian or Other Pacific Islander	0	1	
Unknown	4	11	

End points

End points reporting groups

Reporting group title	Futibatinib (Cohort 1)
Reporting group description: Subjects with advanced or metastatic hormone receptor – positive (HR+), human epidermal growth factor receptor 2 - negative (HER2-) breast cancer, harboring fibroblast growth factor receptor 2 (FGFR2) gene amplification, with measurable disease received futibatinib, 20 milligrams (mg), oral tablets, once daily for a continuous 28-day cycle up to maximum of 244 days.	
Reporting group title	Futibatinib (Cohort 2)
Reporting group description: Subjects with advanced or metastatic triple negative breast cancer (TNBC), harboring FGFR2 gene amplification, with measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 1066 days.	
Reporting group title	Futibatinib (Cohort 3)
Reporting group description: Subjects with advanced or metastatic HR+, HER2- or TNBC, breast cancer harboring FGFR2 gene amplification, with non-measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 252 days.	
Reporting group title	Futibatinib Plus Fulvestrant (Cohort 4)
Reporting group description: Subjects with advanced or metastatic HR+ HER2- breast cancer, harboring FGFR1 gene amplification, with measurable disease, received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 645 days. They also received intramuscular (IM) fulvestrant 500 mg on Days 1 and 15 of Cycle 1 and Day 1 of every subsequent cycle up to maximum of 618 days.	

Primary: Objective Response Rate (ORR) - Cohorts 1, 2

End point title	Objective Response Rate (ORR) - Cohorts 1, 2 ^{[1][2]}
End point description: ORR was defined as the percentage of subjects with a confirmed response of either complete response (CR) or partial response (PR), 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 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 enrolled 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 40 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.

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

Justification: This outcome measure was planned to be reported for only Cohort 1 and 2 as pre-specified in Protocol and SAP.

End point values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17 ^[3]	21		
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0 to 19.5)	9.5 (1.2 to 30.4)		

Notes:

[3] - No subjects achieved response.

Statistical analyses

No statistical analyses for this end point

Primary: Clinical Benefit Rate (CBR) - Cohort 3

End point title	Clinical Benefit Rate (CBR) - Cohort 3 ^{[4][5]}
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End point description:

CBR was defined as the percentage of subjects with confirmed CR or SD lasting ≥ 24 weeks by Investigator assessment. CR: disappearance of all target lesions, with any pathological lymph node reduced to < 10 mm short axis. SD: neither sufficient shrinkage for PR nor sufficient increase for PD, referencing the smallest sum diameters on study. PR: $\geq 30\%$ decrease in sum of target lesion diameters from baseline. PD: $\geq 20\%$ increase in sum diameters from the smallest on study (including baseline), plus ≥ 5 mm absolute increase, or new lesions. Percentages were rounded off to the nearest single decimal place. All treated population included all enrolled subjects who received at least 1 dose of study drug.

End point type	Primary
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End point timeframe:

At the end of every 2 cycles until disease progression (up to 40 months)

Notes:

[4] - 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.

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

Justification: This outcome measure was planned to be reported for only Cohort 3 as pre-specified in Protocol and SAP.

End point values	Futibatinib (Cohort 3)			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: percentage of subjects				
number (confidence interval 95%)	50.0 (6.8 to 93.2)			

Statistical analyses

No statistical analyses for this end point

Primary: 6-month Progression-free Survival (PFS) Rate - Cohort 4

End point title	6-month Progression-free Survival (PFS) Rate - Cohort 4 ^{[6][7]}
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End point description:

The 6-month PFS rate was defined as the proportion percentage of subjects who are alive and

progression-free 6 months after the first dose of study drug. Percentages were rounded off to the nearest single decimal place. All treated population included all enrolled subjects who received at least 1 dose of study drug.

End point type	Primary
End point timeframe:	
6 months	

Notes:

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

Justification: Only descriptive statistics is provided for this end point.

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

Justification: This outcome measure was planned to be reported for only Cohort 4 as pre-specified in Protocol and SAP.

End point values	Futibatinib Plus Fulvestrant (Cohort 4)			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: percentage of subjects				
number (confidence interval 95%)	45.5 (24.4 to 67.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response (CR) Rate - Cohort 3

End point title	Complete Response (CR) Rate - Cohort 3 ^[8]
End point description:	
CR rate was defined as the percentage of subjects who achieved CR. CR was defined as disappearance of all targets. Any pathological lymph node must have reduction in short axis to <10 mm. Percentages were rounded off to the nearest single decimal place. All treated population included all enrolled 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 40 months)

Notes:

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

Justification: This outcome measure was planned to be reported for only Cohort 3 as pre-specified in Protocol and SAP.

End point values	Futibatinib (Cohort 3)			
Subject group type	Reporting group			
Number of subjects analysed	4 ^[9]			
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 60.2)			

Notes:

[9] - No subjects achieved response.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) - Cohort 4

End point title	Overall Response Rate (ORR) - Cohort 4 ^[10]
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End point description:

ORR was defined as the percentage of subjects with a confirmed response of either CR or PR, 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 enrolled 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 40 months)

Notes:

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

Justification: This outcome measure was planned to be reported for only Cohort 4 as pre-specified in Protocol and SAP.

End point values	Futibatinib Plus Fulvestrant (Cohort 4)			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: percentage of subjects				
number (confidence interval 95%)	18.2 (5.2 to 40.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Benefit Rate (CBR) - Cohort 1, 2, and 4

End point title	Clinical Benefit Rate (CBR) - Cohort 1, 2, and 4 ^[11]
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End point description:

CBR was defined as the percentage of subjects with confirmed CR or SD lasting ≥ 24 weeks by Investigator assessment. CR: disappearance of all target lesions, with any pathological lymph node reduced to <10 mm short axis. SD: neither sufficient shrinkage for PR nor sufficient increase for PD, referencing the smallest sum diameters on study. PR: $\geq 30\%$ decrease in sum of target lesion diameters from baseline. PD: $\geq 20\%$ increase in sum diameters from the smallest on study (including baseline), plus ≥ 5 mm absolute increase, or new lesions. Percentages were rounded off to the nearest single decimal place. All treated population included all enrolled 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 40 months)

Notes:

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

Justification: This outcome measure was planned to be reported for only Cohort 1, 2, and 4 as pre-specified in Protocol and SAP.

End point values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib Plus Fulvestrant (Cohort 4)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	21	22	
Units: percentage of subjects				
number (confidence interval 95%)	11.8 (1.5 to 36.4)	23.8 (8.2 to 47.2)	50.0 (28.2 to 71.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: 6-month PFS Rate - Cohorts 1, 2 and 3

End point title	6-month PFS Rate - Cohorts 1, 2 and 3 ^[12]
End point description: The 6-month PFS rate was defined as the percentage of subjects who are alive and progression-free 6 months after the first dose of study drug. Percentages were rounded off to the nearest single decimal place. All treated population included all enrolled subjects who received at least 1 dose of study drug.	
End point type	Secondary
End point timeframe: 6 months	

Notes:

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

Justification: This outcome measure was planned to be reported for only Cohort 1, 2 and 3 as pre-specified in Protocol and SAP.

End point values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	21	4	
Units: percentage of subjects				
number (confidence interval 95%)	5.9 (0.1 to 28.7)	19.0 (5.4 to 41.9)	50.0 (6.8 to 93.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

End point title	Progression-free Survival (PFS)
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End point description:

PFS was defined as the time from the first dose of study therapy to the date of death (any cause) or disease progression based on investigator assessment, whichever occurs first. The PFS was analyzed 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. '9999' signifies that upper limit of 95% CI was not estimable due to a lack of sufficient number of events within the cohort to estimate the parameter. All treated population included all enrolled 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 40 months)

End point values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)	Futibatinib Plus Fulvestrant (Cohort 4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	4	22
Units: Months				
median (confidence interval 95%)	3.7 (1.7 to 5.1)	1.9 (1.6 to 4.0)	12.4 (1.9 to 9999)	7.2 (2.1 to 7.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)
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End point description:

DOR was defined as the time from the first documentation of objective response to the to the date of death (any cause) or disease progression, based on Investigator assessment, whichever occurs first. Objective response was defined as subjects with a confirmed response of either CR or PR, 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. DOR was estimated using the Kaplan-Meier method. All treated population included all enrolled subjects who received at least 1 dose of study drug. Number of subjects analysed are the subjects with data available for analysis.

End point type	Secondary
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End point timeframe:

At the end of every 2 cycles until disease progression (up to 40 months)

End point values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)	Futibatinib Plus Fulvestrant (Cohort 4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[13]	2	0 ^[14]	4
Units: months				
median (full range (min-max))	(to)	3.38 (3.1 to 3.7)	(to)	6.34 (3.3 to 16.7)

Notes:

[13] - No subject had an event

[14] - No subject had an event

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 (in months) from the date of first dose of the study drug to the date of death. 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. 999 signifies that upper limit of 95% CI was not estimable because there was no event time for which the upper bound of the CI for the Kaplan-Meier estimate was less than 0.5

End point type	Secondary
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End point timeframe:

Up to 40 months

End point values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)	Futibatinib Plus Fulvestrant (Cohort 4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	4	22
Units: months				
median (confidence interval 95%)	16.5 (8.1 to 999)	10.2 (6.1 to 21.8)	30.4 (12.4 to 999)	23.9 (20.6 to 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Adverse Events (AEs)

End point title	Number of Subjects with Adverse Events (AEs)
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End point description:

An 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. All treated population included all enrolled 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 40 months).

End point values	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)	Futibatinib Plus Fulvestrant (Cohort 4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	4	22
Units: Count of subjects				
number (not applicable)	17	21	4	22

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Dose Limiting Toxicities (DLTs) – Cohort 4

End point title	Number of Subjects With Dose Limiting Toxicities (DLTs) – Cohort 4 ^[15]
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End point description:

A DLT was defined as any AE that occurs during Cycle 1 that is not clearly attributable to an extraneous cause, such as an underlying disease, occurring in Cycle 1, and meeting at least one of the criteria defined in the protocol. An AE is defined as any untoward medical occurrence in a clinical study subjects and does not necessarily have a causal relationship with the study drug. All treated population included all enrolled subjects who received at least 1 dose of study drug.

End point type	Secondary
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End point timeframe:

Cycle 1 (up to 28 days)

Notes:

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

Justification: This outcome measure was planned to be reported for only Cohort 4 as pre-specified in Protocol and SAP.

End point values	Futibatinib Plus Fulvestrant (Cohort 4)			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: Subjects				
number (not applicable)	0			

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 40 months)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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Reporting groups

Reporting group title	Futibatinib (Cohort 1)
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Reporting group description:

Subjects with advanced or metastatic hormone receptor – positive (HR+), human epidermal growth factor receptor 2 - negative (HER2-) breast cancer, harboring fibroblast growth factor receptor 2 (FGFR2) gene amplification, with measurable disease received futibatinib, 20 milligrams (mg), oral tablets, once daily for a continuous 28-day cycle up to maximum of 244 days.

Reporting group title	Futibatinib (Cohort 2)
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Reporting group description:

Subjects with advanced or metastatic triple negative breast cancer (TNBC), harboring FGFR2 gene amplification, with measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 1066 days.

Reporting group title	Futibatinib (Cohort 3)
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Reporting group description:

Subjects with advanced or metastatic HR+, HER2- or TNBC, breast cancer harboring FGFR2 gene amplification, with non-measurable disease received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 252 days.

Reporting group title	Futibatinib Plus Fulvestrant (Cohort 4)
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Reporting group description:

Subjects with advanced or metastatic HR+ HER2- breast cancer, harboring FGFR1 gene amplification, with measurable disease, received futibatinib, 20 mg, oral tablets, once daily for a continuous 28-day cycle up to maximum of 645 days. They also received intramuscular (IM) fulvestrant 500 mg on Days 1 and 15 of Cycle 1 and Day 1 of every subsequent cycle up to maximum of 618 days.

Serious adverse events	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 17 (23.53%)	5 / 21 (23.81%)	1 / 4 (25.00%)
number of deaths (all causes)	10	14	2
number of deaths resulting from adverse events	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (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
Pericardial effusion malignant			

subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hepatic encephalopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			

subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic ischaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (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
Urinary tract obstruction			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
Hyperphosphataemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Futibatinib Plus Fulvestrant (Cohort 4)		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 22 (18.18%)		
number of deaths (all causes)	7		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute promyelocytic leukaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion malignant			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Hepatic encephalopathy			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Ischaemic stroke			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Intestinal obstruction			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Volvulus			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatic ischaemia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic failure			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pathological fracture			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperphosphataemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Futibatinib (Cohort 1)	Futibatinib (Cohort 2)	Futibatinib (Cohort 3)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 17 (94.12%)	21 / 21 (100.00%)	4 / 4 (100.00%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			

subjects affected / exposed	4 / 17 (23.53%)	7 / 21 (33.33%)	3 / 4 (75.00%)
occurrences (all)	4	8	3
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	3 / 21 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Mucosal inflammation			
subjects affected / exposed	0 / 17 (0.00%)	3 / 21 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Malaise			
subjects affected / exposed	0 / 17 (0.00%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
Vulvovaginal dryness			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Investigations			
Aspartate aminotransferase increased			

subjects affected / exposed	7 / 17 (41.18%)	5 / 21 (23.81%)	0 / 4 (0.00%)
occurrences (all)	9	5	0
Alanine aminotransferase increased			
subjects affected / exposed	4 / 17 (23.53%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	5	2	0
Weight decreased			
subjects affected / exposed	4 / 17 (23.53%)	4 / 21 (19.05%)	1 / 4 (25.00%)
occurrences (all)	4	5	1
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 17 (11.76%)	3 / 21 (14.29%)	1 / 4 (25.00%)
occurrences (all)	2	3	1
Blood bilirubin increased			
subjects affected / exposed	2 / 17 (11.76%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
White blood cell count decreased			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Blood cholesterol increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Blood phosphorus increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Blood triglycerides increased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 21 (0.00%) 0	0 / 4 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 21 (4.76%) 1	0 / 4 (0.00%) 0
Computerised tomogram abnormal subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 21 (0.00%) 0	0 / 4 (0.00%) 0
Nervous system disorders			
Dysgeusia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 21 (0.00%) 0	2 / 4 (50.00%) 2
Headache subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 4	2 / 21 (9.52%) 2	0 / 4 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 21 (0.00%) 0	1 / 4 (25.00%) 1
Taste disorder subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 21 (4.76%) 1	0 / 4 (0.00%) 0
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 21 (0.00%) 0	0 / 4 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 21 (4.76%) 1	1 / 4 (25.00%) 1
Dizziness subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 21 (0.00%) 0	1 / 4 (25.00%) 1
Seizure subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 2	1 / 21 (4.76%) 1	0 / 4 (0.00%) 0
Somnolence			

subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 17 (0.00%)	1 / 21 (4.76%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Epilepsy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Parosmia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 17 (23.53%)	5 / 21 (23.81%)	0 / 4 (0.00%)
occurrences (all)	4	5	0
Neutropenia			
subjects affected / exposed	2 / 17 (11.76%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Lymph node pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye disorders			

Dry eye			
subjects affected / exposed	2 / 17 (11.76%)	5 / 21 (23.81%)	2 / 4 (50.00%)
occurrences (all)	2	5	2
Ocular hyperaemia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Vision blurred			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Conjunctival hyperaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Central serous chorioretinopathy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Corneal disorder			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Growth of eyelashes			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	8 / 17 (47.06%)	9 / 21 (42.86%)	1 / 4 (25.00%)
occurrences (all)	8	9	1
Diarrhoea			
subjects affected / exposed	4 / 17 (23.53%)	8 / 21 (38.10%)	1 / 4 (25.00%)
occurrences (all)	4	12	1
Nausea			

subjects affected / exposed	7 / 17 (41.18%)	6 / 21 (28.57%)	0 / 4 (0.00%)
occurrences (all)	7	8	0
Dry mouth			
subjects affected / exposed	5 / 17 (29.41%)	4 / 21 (19.05%)	1 / 4 (25.00%)
occurrences (all)	5	4	1
Vomiting			
subjects affected / exposed	2 / 17 (11.76%)	4 / 21 (19.05%)	1 / 4 (25.00%)
occurrences (all)	4	8	1
Abdominal pain			
subjects affected / exposed	3 / 17 (17.65%)	1 / 21 (4.76%)	1 / 4 (25.00%)
occurrences (all)	3	1	1
Stomatitis			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Abdominal pain upper			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 17 (5.88%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 17 (5.88%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Dysphagia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Oral pain			
subjects affected / exposed	1 / 17 (5.88%)	1 / 21 (4.76%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Dental caries			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hepatobiliary disorders			

Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 21 (0.00%) 0	0 / 4 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 4	3 / 21 (14.29%) 3	1 / 4 (25.00%) 1
Dry skin subjects affected / exposed occurrences (all)	3 / 17 (17.65%) 3	6 / 21 (28.57%) 6	0 / 4 (0.00%) 0
Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	1 / 21 (4.76%) 1	1 / 4 (25.00%) 1
Onycholysis subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	3 / 21 (14.29%) 3	0 / 4 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	3 / 17 (17.65%) 3	1 / 21 (4.76%) 1	2 / 4 (50.00%) 2
Nail disorder subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 21 (4.76%) 1	1 / 4 (25.00%) 1
Rash subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 21 (4.76%) 1	0 / 4 (0.00%) 0
Nail discolouration subjects affected / exposed occurrences (all)	3 / 17 (17.65%) 3	0 / 21 (0.00%) 0	0 / 4 (0.00%) 0
Nail dystrophy subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 21 (0.00%) 0	0 / 4 (0.00%) 0
Pain of skin subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 21 (0.00%) 0	1 / 4 (25.00%) 1
Dermal cyst			

subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Onychomadesis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 17 (11.76%)	4 / 21 (19.05%)	2 / 4 (50.00%)
occurrences (all)	2	5	2
Muscle spasms			
subjects affected / exposed	3 / 17 (17.65%)	3 / 21 (14.29%)	2 / 4 (50.00%)
occurrences (all)	4	3	2
Back pain			
subjects affected / exposed	1 / 17 (5.88%)	2 / 21 (9.52%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Myalgia			
subjects affected / exposed	1 / 17 (5.88%)	4 / 21 (19.05%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 17 (11.76%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	2 / 17 (11.76%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Groin pain			

subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	2 / 17 (11.76%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
COVID-19			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye infection			
subjects affected / exposed	0 / 17 (0.00%)	2 / 21 (9.52%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Oral candidiasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Herpes simplex reactivation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperphosphataemia			

subjects affected / exposed	13 / 17 (76.47%)	18 / 21 (85.71%)	3 / 4 (75.00%)
occurrences (all)	14	27	4
Decreased appetite			
subjects affected / exposed	2 / 17 (11.76%)	4 / 21 (19.05%)	1 / 4 (25.00%)
occurrences (all)	2	4	1
Hypercalcaemia			
subjects affected / exposed	3 / 17 (17.65%)	3 / 21 (14.29%)	0 / 4 (0.00%)
occurrences (all)	3	3	0
Hypertriglyceridaemia			
subjects affected / exposed	2 / 17 (11.76%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 21 (9.52%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Hypomagnesaemia			
subjects affected / exposed	0 / 17 (0.00%)	3 / 21 (14.29%)	1 / 4 (25.00%)
occurrences (all)	0	5	1
Hypophosphataemia			
subjects affected / exposed	0 / 17 (0.00%)	3 / 21 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	7	0
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	2 / 21 (9.52%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Hyperkalaemia			
subjects affected / exposed	2 / 17 (11.76%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oral dysaesthesia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 21 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Futibatinib Plus Fulvestrant (Cohort 4)		
Total subjects affected by non-serious adverse events			

subjects affected / exposed	22 / 22 (100.00%)		
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	7 / 22 (31.82%)		
occurrences (all)	7		
Asthenia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Mucosal inflammation			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Vulvovaginal dryness			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

Sleep disorder subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	11 / 22 (50.00%) 11		
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	13 / 22 (59.09%) 20		
Weight decreased subjects affected / exposed occurrences (all)	6 / 22 (27.27%) 6		
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	6 / 22 (27.27%) 7		
Blood bilirubin increased subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1		
Lymphocyte count decreased subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
Neutrophil count decreased subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1		
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Blood phosphorus increased			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Blood triglycerides increased			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Computerised tomogram abnormal			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	5 / 22 (22.73%)		
occurrences (all)	5		
Headache			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Taste disorder			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Neuropathy peripheral			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dizziness			

subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Seizure			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Transient ischaemic attack			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Tremor			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Epilepsy			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Parosmia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Neutropenia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	2		
Lymph node pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Eye disorders Dry eye subjects affected / exposed occurrences (all) Ocular hyperaemia subjects affected / exposed occurrences (all) Vision blurred subjects affected / exposed occurrences (all) Conjunctival hyperaemia subjects affected / exposed occurrences (all) Vitreous floaters subjects affected / exposed occurrences (all) Central serous chorioretinopathy subjects affected / exposed occurrences (all) Corneal disorder subjects affected / exposed occurrences (all) Eye pain subjects affected / exposed occurrences (all) Growth of eyelashes subjects affected / exposed occurrences (all)	7 / 22 (31.82%) 7 1 / 22 (4.55%) 1 1 / 22 (4.55%) 1 1 / 22 (4.55%) 1 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0		
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Diarrhoea	13 / 22 (59.09%) 13		

subjects affected / exposed	10 / 22 (45.45%)		
occurrences (all)	18		
Nausea			
subjects affected / exposed	9 / 22 (40.91%)		
occurrences (all)	9		
Dry mouth			
subjects affected / exposed	10 / 22 (45.45%)		
occurrences (all)	10		
Vomiting			
subjects affected / exposed	7 / 22 (31.82%)		
occurrences (all)	7		
Abdominal pain			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	5		
Stomatitis			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	4		
Abdominal pain upper			
subjects affected / exposed	5 / 22 (22.73%)		
occurrences (all)	6		
Dyspepsia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Dysphagia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Oral pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dental caries			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Toothache			

subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	13 / 22 (59.09%) 13		
Dry skin subjects affected / exposed occurrences (all)	5 / 22 (22.73%) 5		
Palmar-plantar erythrodysesthesia syndrome subjects affected / exposed occurrences (all)	5 / 22 (22.73%) 5		
Onycholysis subjects affected / exposed occurrences (all)	3 / 22 (13.64%) 3		
Pruritus subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1		
Nail disorder subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
Rash subjects affected / exposed occurrences (all)	3 / 22 (13.64%) 3		
Nail discolouration subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Nail dystrophy subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
Pain of skin			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dermal cyst			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Onychomadesis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 22 (31.82%)		
occurrences (all)	8		
Muscle spasms			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Back pain			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	4		
Myalgia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Pain in extremity			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	4		
Flank pain			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Pain in jaw			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Eye infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Erysipelas			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Herpes simplex reactivation			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		

Metabolism and nutrition disorders			
Hyperphosphataemia			
subjects affected / exposed	21 / 22 (95.45%)		
occurrences (all)	35		
Decreased appetite			
subjects affected / exposed	7 / 22 (31.82%)		
occurrences (all)	7		
Hypercalcaemia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Hypertriglyceridaemia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Hyperglycaemia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Dehydration			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oral dysaesthesia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 June 2019	The following changes were made as per amendment 1: 1.Added plasma sample collection for PopPK analyses; this included the addition of a corresponding exploratory objective. 2. Added of Section describing collection and analysis of samples, and additions / amendments to the statistical methods defining the PopPK analysis set and discussing analysis and summarization of data. 3. Updated inclusion Criterion with several clarifications related to permitted prior therapies. 4. Increased the required duration of contraception to 1 year after last dose of fulvestrant. 5. The definition of a DLT was modified per regulatory feedback. 6. Specified that for Cohort 4, in cases where toxicity is not clearly attributable to either study drug, TAS-120 will be modified or discontinued first.

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 decided to discontinue the study due to strategic considerations and not due to any safety-related concerns.

Notes: