Clinical trial results:
An Open-Label Extension Study to Allow Continued Dosing and/or Follow-up of Patients who have had Previous Exposure to Poziotinib

Summary

EudraCT number	2020-005213-40
Trial protocol	IT
Global end of trial date	03 March 2023

Results information

Result version number	v1 (current)
This version publication date	19 April 2024
First version publication date	19 April 2024

Trial information

Trial identification

Sponsor protocol code	SPI-POZ-501

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03744715
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Spectrum Pharmaceuticals, Inc.
Sponsor organisation address	Research and Development Office, 157 Technology Dr W, Irvine, California, United States, 92618
Public contact	Howard Franklin, Assertio Holdings, 00 224 419 7106, Hfranklin@assertiotx.com
Scientific contact	Howard Franklin, Assertio Holdings, 00 224 419 7106, Hfranklin@assertiotx.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	03 March 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this extension study was to provide the clinical benefit of poziotinib to participants who were responding to treatment.

Protection of trial subjects:

This study was conducted in accordance with good clinical practice (GCP) and with the internal standard operating procedures (SOPs) of Spectrum Pharmaceuticals, Inc. A study-specific written informed consent was signed by each subject prior to any study-related assessments or procedures that were conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 7
Worldwide total number of subjects	7
EEA total number of subjects	0

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)	4
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at investigative sites across the United States from 11 October 2018 to 03 March 2023.

Pre-assignment

Screening details:

A total of 7 participants were enrolled and dosed with Poziotinib.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Poziotinib 6 mg

Arm description:

Participants started poziotinib 6 mg twice a day (BID) in a 21-day cycle in the current study after having received 16 mg once daily (QD) in the parent study NCT03318939.

Arm type	Experimental
Investigational medicinal product name	Poziotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Modified-release tablet
Routes of administration	Oral use

Dosage and administration details:

Poziotinib 6 mg administered orally, once daily

Arm title	Poziotinib 8 mg

Arm description:

Participants started poziotinib 8 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.

Arm type	Experimental
Investigational medicinal product name	Poziotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Modified-release tablet
Routes of administration	Oral use

Dosage and administration details:

Poziotinib 8 mg administered orally, once daily

Arm title	Poziotinib 12 mg

Arm description:

Participants started poziotinib 12 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT03318939.

Arm type	Experimental

Investigational medicinal product name	Poziotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Modified-release tablet
Routes of administration	Oral use

Dosage and administration details:

Poziotinib 12 mg administered orally, once daily

Arm title	Poziotinib 14 mg

Arm description:

Participants started poziotinib 14 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.

Arm type	Experimental
Investigational medicinal product name	Poziotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Modified-release tablet
Routes of administration	Oral use

Dosage and administration details:

Poziotinib 14 mg administered orally, once daily

Arm title	Poziotinib 16 mg

Arm description:

Participants started poziotinib at 16 mg QD in a 21-day cycle in the current study after having received 12 mg QD in the parent study NCT03804515.

Arm type	Experimental
Investigational medicinal product name	Poziotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Modified-release tablet
Routes of administration	Oral use

Dosage and administration details:

Poziotinib 16 mg administered orally, once daily

Arm title	Poziotinib 24 mg

Arm description:

Participants started poziotinib at 24 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT02659514.

Arm type	Experimental
Investigational medicinal product name	Poziotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Modified-release tablet
Routes of administration	Oral use

Dosage and administration details:

Poziotinib 24 mg administered orally, once daily

Number of subjects in period 1	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg
Started	1	1	1
Completed	0	0	0
Not completed	1	1	1
Initiation of another anti-malignancy therapy	-	-	1
Consent withdrawn by subject	-	-	-
Disease progression	-	1	-
Adverse event, non-fatal	-	-	-
Study terminated by sponsor	1	-	-

Number of subjects in period 1	Poziotinib 14 mg	Poziotinib 16 mg	Poziotinib 24 mg
Started	1	2	1
Completed	0	0	0
Not completed	1	2	1
Initiation of another anti-malignancy therapy	-	-	-
Consent withdrawn by subject	1	-	-
Disease progression	-	1	1
Adverse event, non-fatal	-	1	-
Study terminated by sponsor	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Poziotinib 6 mg
Reporting group description:	
Participants started poziotinib 6 mg twice a day (BID) in a 21-day cycle in the current study after having received 16 mg once daily (QD) in the parent study NCT03318939.	
Reporting group title	Poziotinib 8 mg
Reporting group description:	
Participants started poziotinib 8 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.	
Reporting group title	Poziotinib 12 mg
Reporting group description:	
Participants started poziotinib 12 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT03318939.	
Reporting group title	Poziotinib 14 mg
Reporting group description:	
Participants started poziotinib 14 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.	
Reporting group title	Poziotinib 16 mg
Reporting group description:	
Participants started poziotinib at 16 mg QD in a 21-day cycle in the current study after having received 12 mg QD in the parent study NCT03804515.	
Reporting group title	Poziotinib 24 mg
Reporting group description:	
Participants started poziotinib at 24 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT02659514.	

Reporting group values	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg
Number of subjects	1	1	1
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)	0	0	0
From 65-84 years	1	1	1
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	1	1
Male	1	0	0

Reporting group values	Poziotinib 14 mg	Poziotinib 16 mg	Poziotinib 24 mg
Number of subjects	1	2	1

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)	1	2	1
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	1	1
Male	1	1	0

Reporting group values	Total		
Number of subjects	7		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	4		
From 65-84 years	3		
85 years and over	0		
Gender categorical Units: Subjects			
Female	4		
Male	3		

End points

End points reporting groups

Reporting group title	Poziotinib 6 mg
Reporting group description:	
Participants started poziotinib 6 mg twice a day (BID) in a 21-day cycle in the current study after having received 16 mg once daily (QD) in the parent study NCT03318939.	
Reporting group title	Poziotinib 8 mg
Reporting group description:	
Participants started poziotinib 8 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.	
Reporting group title	Poziotinib 12 mg
Reporting group description:	
Participants started poziotinib 12 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT03318939.	
Reporting group title	Poziotinib 14 mg
Reporting group description:	
Participants started poziotinib 14 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.	
Reporting group title	Poziotinib 16 mg
Reporting group description:	
Participants started poziotinib at 16 mg QD in a 21-day cycle in the current study after having received 12 mg QD in the parent study NCT03804515.	
Reporting group title	Poziotinib 24 mg
Reporting group description:	
Participants started poziotinib at 24 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT02659514.	

Primary: Number of Participants With Adverse Events (AEs)

End point title	Number of Participants With Adverse Events (AEs)[1]
End point description:	
An AE is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. Analysis population included all participants who had previous exposure to poziotinib. The Safety Analysis Population included all the enrolled participants who received at least one dose of poziotinib.	
End point type	Primary
End point timeframe:	
Up to 40 days after the last dose of the study drug (Up to 197 weeks)	

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 analysis was planned for this endpoint.

End point values	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg	Poziotinib 14 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	1	1
Units: subjects				
Number of Participants With Adverse Events (AEs)	1	1	1	1

End point values	Poziotinib 16 mg	Poziotinib 24 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: subjects				
Number of Participants With Adverse Events (AEs)	2	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR)

End point title	Overall Response Rate (ORR)

End point description:

ORR was defined as the percentage of participants with confirmed complete response (CR) and partial response (PR) as assessed by the investigator using local radiology evaluation according to Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1). CR is defined as the disappearance of all target and non-target lesions. Any pathological lymph nodes must have a reduction in the short axis to <10 millimeters (mm). PR is defined as at least a 30% decrease in the sum of diameters of all target lesions, taking as reference the baseline sum of diameters, in the absence of CR. As the study was terminated early due to a business decision, with lack of enrollment, the data for this outcome measure was not collected or analyzed as planned.

End point type	Secondary

End point timeframe:

Up to 191 weeks

End point values	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg	Poziotinib 14 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[2]	0[3]	0[4]	0[5]
Units: percentage of subjects				
Overall Number of Participants Analyzed				

Notes:

[2] - The study was terminated early due to business decision, the data was not analyzed as planned.

[3] - The study was terminated early due to business decision, the data was not analyzed as planned.

[4] - The study was terminated early due to business decision, the data was not analyzed as planned.

[5] - The study was terminated early due to business decision, the data was not analyzed as planned.

End point values	Poziotinib 16 mg	Poziotinib 24 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[6]	0[7]		
Units: percentage of subjects				
Overall Number of Participants Analyzed				

Notes:

[6] - The study was terminated early due to business decision, the data was not analyzed as planned.

[7] - The study was terminated early due to business decision, the data was not analyzed as planned.

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR)

End point title	Disease Control Rate (DCR)

End point description:

DCR is defined as percentage of participants with best response of CR, PR, and stable disease (SD) from the first dose of poziotinib to the end of study. CR is defined as disappearance of all target and non-target lesions. Any pathological lymph nodes must have reduction in short axis to <10 mm. PR is defined as at least a 30% decrease in the sum of diameters of all target lesions, taking as reference the baseline sum of diameters, in the absence of CR. SD is defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD), taking as reference the smallest sum diameters while on study. As the study was terminated early due to a business decision, with lack of enrollment, the data for this outcome measure was not collected or analyzed as planned.

End point type	Secondary

End point timeframe:

Up to 191 weeks

End point values	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg	Poziotinib 14 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[8]	0[9]	0[10]	0[11]
Units: percentage of subjects				
Overall Number of Participants Analyzed				

Notes:

[8] - The study was terminated early due to business decision, the data was not analyzed as planned.

[9] - The study was terminated early due to business decision, the data was not analyzed as planned.

[10] - The study was terminated early due to business decision, the data was not analyzed as planned.

[11] - The study was terminated early due to business decision, the data was not analyzed as planned.

End point values	Poziotinib 16 mg	Poziotinib 24 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[12]	0[13]		
Units: percentage of subjects				
Overall Number of Participants Analyzed				

Notes:

[12] - The study was terminated early due to business decision, the data was not analyzed as planned.

[13] - The study was terminated early due to business decision, the data was not analyzed as planned.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

Duration of response was defined as the time from the date that measurement criteria are first met for CR or PR until the first subsequent date that progressive disease or death is documented. CR is defined as the disappearance of all target and non-target lesions. Any pathological lymph nodes must have a reduction in the short axis to <10 mm. PR is defined as at least a 30% decrease in the sum of diameters of all target lesions, taking as reference the baseline sum of diameters, in the absence of CR. Disease progression is defined as ≥20% increase in the sum of diameters of target lesions, unequivocal progression in non-target lesions, and/or appearance of new lesions. As the study was terminated early due to a business decision, with lack of enrollment, the data for this outcome measure was not collected or analyzed as planned.

End point type	Secondary

End point timeframe:

Up to 191 Weeks

End point values	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg	Poziotinib 14 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[14]	0[15]	0[16]	0[17]
Units: Months				
Overall Number of Participants Analyzed				

Notes:

[14] - The study was terminated early due to business decision, the data was not analyzed as planned.

[15] - The study was terminated early due to business decision, the data was not analyzed as planned.

[16] - The study was terminated early due to business decision, the data was not analyzed as planned.

[17] - The study was terminated early due to business decision, the data was not analyzed as planned.

End point values	Poziotinib 16 mg	Poziotinib 24 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[18]	0[19]		
Units: Months				
Overall Number of Participants Analyzed				

Notes:

[18] - The study was terminated early due to business decision, the data was not analyzed as planned.

[19] - The study was terminated early due to business decision, the data was not analyzed as planned.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

PFS was the duration of time from first administration of study treatment to date of first documented disease progression or death from any cause. Per RECIST v1.1 for target lesions, PD was defined as ≥20% increase in the sum of diameters of target lesions, unequivocal progression in non-target lesions, and/or appearance of new lesions. As the study was terminated early due to a business decision, with lack of enrollment, the data for this outcome measure was not collected or analyzed as planned.

End point type	Secondary

End point timeframe:

Up to 191 Weeks

End point values	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg	Poziotinib 14 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[20]	0[21]	0[22]	0[23]
Units: Months				
Overall Number of Participants Analyzed				

Notes:

[20] - The study was terminated early due to business decision, the data was not analyzed as planned.

[21] - The study was terminated early due to business decision, the data was not analyzed as planned.

[22] - The study was terminated early due to business decision, the data was not analyzed as planned.

[23] - The study was terminated early due to business decision, the data was not analyzed as planned.

End point values	Poziotinib 16 mg	Poziotinib 24 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[24]	0[25]		
Units: Months				
Overall Number of Participants Analyzed				

Notes:

[24] - The study was terminated early due to business decision, the data was not analyzed as planned.

[25] - The study was terminated early due to business decision, the data was not analyzed as planned.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 40 days after the last dose of the study drug (Up to 197 weeks)

Adverse event reporting additional description:

The Safety Analysis Population included all the enrolled participants who received at least one dose of poziotinib.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Poziotinib 6 mg

Reporting group description:

Participants started poziotinib 6 mg twice a day (BID) in a 21-day cycle in the current study after having received 16 mg once daily (QD) in the parent study NCT03318939.

Reporting group title	Poziotinib 8 mg

Reporting group description:

Participants started poziotinib 8 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.

Reporting group title	Poziotinib 12 mg

Reporting group description:

Participants started poziotinib 12 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT03318939.

Reporting group title	Poziotinib 14 mg

Reporting group description:

Participants started poziotinib 14 mg QD in a 21-day cycle in the current study after having received 16 mg QD in the parent study NCT03318939.

Reporting group title	Poziotinib 16 mg

Reporting group description:

Participants started poziotinib at 16 mg QD in a 21-day cycle in the current study after having received 12 mg QD in the parent study NCT03804515.

Reporting group title	Poziotinib 24 mg

Reporting group description:

Participants started poziotinib at 24 mg QD in a 21-day cycle in the current study after having received same dose in the parent study NCT02659514.

Serious adverse events	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Ascites			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Poziotinib 14 mg	Poziotinib 16 mg	Poziotinib 24 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Poziotinib 6 mg	Poziotinib 8 mg	Poziotinib 12 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	1	0	1
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Neutrophil count increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Peroneal nerve palsy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
occurrences (all)	0	1	16
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Skin atrophy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
occurrences (all)	0	1	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Poziotinib 14 mg	Poziotinib 16 mg	Poziotinib 24 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 2 (100.00%)	1 / 1 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Investigations			
Amylase Increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Neutrophil count increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Weight decreased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
White blood cell count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	5	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Vomiting			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Dermatitis acneiform			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	7	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Skin atrophy			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hematuria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 1 (100.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	6	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dehydration			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 November 2019	1. This study has been open to all participants who have had previous exposure to poziotinib, including participants in Investigator-Initiated Studies (IIS) as long as the participant is receiving clinical benefit, as judged by the Investigator or treating physician. 2. In order to conduct analyses with data from these participants, specific assessments and their timing have been added: • Addition of a summary of assessments and procedures table. • Assessments must be at least every 2 cycles of treatment • Added detailed explanations for assessments and procedures in Section 5, Study Procedures 3. The participant's last dose before entering the study was changed from "cannot be more than 20 days" to "cannot be more than 28 days". 4. The study title changed to "An Open-Label Extension Study to Allow Continued Dosing and/or Follow-up of Patients who have had Previous Exposure to Poziotinib" from "An Open-Label Extension Study to Allow Continued Treatment of Patients who have Participated in a Spectrum-Sponsored Poziotinib Study". 5. The primary objective changed to "To continue to monitor patients who appear to derive clinical benefit from poziotinib" from "To continue to provide clinical benefit to patients who have participated in Spectrum-sponsored studies with poziotinib". 6. Removal of inclusion criteria "Patient did not meet any treatment discontinuation criteria other than completing maximum treatment time of the original Spectrum-sponsored Study". 7. Removal of exclusion criteria "Patient is receiving any other treatment modalities with curative intent for his or her malignancy, including investigational products other than poziotinib. Therapies to palliate local symptoms will be allowed (e.g. radiation for focal bone metastasis). 8. Addition of exclusion criteria "Patient's last dose of poziotinib was more than 28 days prior to Day 1 of the study".
27 November 2019	9. Removed the reference to SPI-POZ-102 and stated that participants can be treated at their last dose or at 16 mg/day in Section 6.1.3: Poziotinib Administration. 10. Added the standard dose modification instructions that are used in other poziotinib studies in Section 6.4: Poziotinib Dose Delays and Modifications. Dose reductions below 8 mg are not recommended in the study. 11. The evaluation of participants and the collecting of data was formalized in Section 5.1: Screening.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
03 March 2023	Study was terminated due to business reasons, not related to safety.	-

Notes:

Limitations and caveats

None reported