



Clinical trial results:

A Modular Phase IIa Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients with Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE)

Summary

EudraCT number	2020-002529-27
Trial protocol	FR
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	25 February 2026
First version publication date	25 February 2026

Trial information

Trial identification

Sponsor protocol code	D5339C00001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04564027
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca Clinical Study Information Center
Sponsor organisation address	Södertälje, Södertälje, Sweden, 151 85
Public contact	AstraZeneca Clinical study Information Center, AstraZeneca Clinical study Information Center, +1 8772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca Clinical Study Information Center, +1 8772409479, information.center@astrazeneca.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	Interim
Date of interim/final analysis	28 April 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 April 2023
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To obtain a preliminary assessment of the efficacy of ceralasertib in participants with Ataxia telangiectasia mutated (ATM)-altered advanced solid tumour (aST) refractory to standard treatments options, as assessed by Objective response rate (ORR).

Protection of trial subjects:

This study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the International Conference on Harmonisation/Good Clinical Practice, applicable regulatory requirements, and the AstraZeneca policy on Bioethics and Human Biological Samples. Before enrollment of any patient into the study, the final protocol, including the final version of the informed consent form, was approved by the national regulatory authority or a notification to the national regulatory authority was done, according to local regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 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	Spain: 5
Country: Number of subjects enrolled	France: 19
Country: Number of subjects enrolled	United States: 30
Worldwide total number of subjects	54
EEA total number of subjects	24

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)	17
From 65 to 84 years	37

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Participants were enrolled in this study from 01 December 2020 to 04 April 2023 at 18 centers in 3 countries.

Pre-assignment

Screening details:

The screening comprised of 2 parts, Part 1 and Part 2, which applied for both Cohort A and Cohort B. Participants meeting the inclusion criteria were enrolled in the study. All the assessments were performed as per the schedule of the assessments.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A (aST): 240 mg of Ceralasertib

Arm description:

Participants with Ataxia telangiectasia mutated (ATM) altered Advanced solid tumour (aST) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Arm type	Experimental
Investigational medicinal product name	240 mg of Ceralasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 240 mg of ceralasertib in the Cohort A of the study

Arm title	Cohort A (aST): 160 mg of Ceralasertib
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Arm description:

Participants with ATM-altered aST received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Arm type	Experimental
Investigational medicinal product name	160 mg of ceralasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 160 mg of ceralasertib in the Cohort A of the study

Arm title	Cohort B (mCRPC): 240 mg of Ceralasertib
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Arm description:

Participants with ATM-altered Metastatic castration-resistant prostate cancer (mCRPC) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Arm type	Experimental
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Investigational medicinal product name	240 mg of ceralasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received 240 mg of ceralasertib in the Cohort B of the study	
Arm title	Cohort B (mCRPC): 160 mg of Ceralasertib

Arm description:

Participants with ATM-altered mCRPC received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Arm type	Experimental
Investigational medicinal product name	160 mg of ceralasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 160 mg of ceralasertib in the Cohort B of the study

Number of subjects in period 1	Cohort A (aST): 240 mg of Ceralasertib	Cohort A (aST): 160 mg of Ceralasertib	Cohort B (mCRPC): 240 mg of Ceralasertib
Started	8	30	1
Completed	8	27	1
Not completed	0	3	0
Ongoing treatment as of 28Apr23	-	3	-

Number of subjects in period 1	Cohort B (mCRPC): 160 mg of Ceralasertib
Started	15
Completed	15
Not completed	0
Ongoing treatment as of 28Apr23	-

Baseline characteristics

Reporting groups

Reporting group title	Cohort A (aST): 240 mg of Ceralasertib
Reporting group description: Participants with Ataxia telangiectasia mutated (ATM) altered Advanced solid tumour (aST) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	
Reporting group title	Cohort A (aST): 160 mg of Ceralasertib
Reporting group description: Participants with ATM-altered aST received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	
Reporting group title	Cohort B (mCRPC): 240 mg of Ceralasertib
Reporting group description: Participants with ATM-altered Metastatic castration-resistant prostate cancer (mCRPC) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	
Reporting group title	Cohort B (mCRPC): 160 mg of Ceralasertib
Reporting group description: Participants with ATM-altered mCRPC received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	

Reporting group values	Cohort A (aST): 240 mg of Ceralasertib	Cohort A (aST): 160 mg of Ceralasertib	Cohort B (mCRPC): 240 mg of Ceralasertib
Number of subjects	8	30	1
Age Categorical Units: Participants			
18-64	3	11	0
65-84	5	19	1
≥ 85	0	0	0
Age continuous Units: years			
arithmetic mean	64.1	65.5	0
standard deviation	± 10.92	± 11.0	± 0
Sex: Female, Male Units: Participants			
Female	5	14	0
Male	3	16	1
Race/Ethnicity, Customized Units: Subjects			
Black or African American	0	0	0
Native Hawaiin or Other Pacific Islander	0	0	0
White	8	11	0
Not Reported	0	7	0
Missing	0	9	0
Other	0	3	1
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	3	0
Not Hispanic or Latino	8	13	1
Missing.	0	14	0

Reporting group values	Cohort B (mCRPC): 160 mg of Ceralasertib	Total	
Number of subjects	15	54	
Age Categorical Units: Participants			
18-64	3	17	
65-84	12	37	
≥ 85	0	0	
Age continuous Units: years arithmetic mean standard deviation	70.7 ± 7.46	-	
Sex: Female, Male Units: Participants			
Female	0	19	
Male	15	35	
Race/Ethnicity, Customized Units: Subjects			
Black or African American	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
White	6	25	
Not Reported	4	11	
Missing	5	14	
Other	0	4	
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	4	
Not Hispanic or Latino	9	31	
Missing.	5	19	

End points

End points reporting groups

Reporting group title	Cohort A (aST): 240 mg of Ceralasertib
Reporting group description: Participants with Ataxia telangiectasia mutated (ATM) altered Advanced solid tumour (aST) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	
Reporting group title	Cohort A (aST): 160 mg of Ceralasertib
Reporting group description: Participants with ATM-altered aST received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	
Reporting group title	Cohort B (mCRPC): 240 mg of Ceralasertib
Reporting group description: Participants with ATM-altered Metastatic castration-resistant prostate cancer (mCRPC) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	
Reporting group title	Cohort B (mCRPC): 160 mg of Ceralasertib
Reporting group description: Participants with ATM-altered mCRPC received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.	

Primary: Cohort A (aST): Objective response rate (ORR)

End point title	Cohort A (aST): Objective response rate (ORR) ^{[1][2]}
End point description: ORR is defined as the percentage of participants who have at least one response of complete response (CR) or partial response (PR) prior to any evidence of progression (as defined by response evaluation criteria in solid tumours [RECIST] 1.1) that is confirmed at least 4 weeks later. The CR is defined as disappearance of all target and non-target lesions and no new lesions. The PR is defined as $\geq 30\%$ decrease in the sum of the diameters of target lesions compared to baseline and no new non-target lesion. Evaluable for response set included all participants who were Molecularly Eligible Centrally Confirmed evaluable for response set with measurable disease at baseline and who received at least 1 dose of study intervention. Due to an increased frequency and early onset of Grade ≥ 3 hematological toxicity on receiving 240 mg of Ceralasertib, the sponsor decreased the dose to 160mg. Therefore, patients with the 240 mg were not included in the efficacy analyses for both study cohorts.	
End point type	Primary
End point timeframe: 2 years 4 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: No formal hypothesis testing was conducted and therefore has not been presented here.

[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: No formal hypothesis testing was conducted and therefore has not been presented here.

End point values	Cohort A (aST): 160 mg of Ceralasertib			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Percentage of participants				
number (confidence interval 80%)	7.14 (1.9 to 17.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort B (mCRPC): Composite response rate

End point title	Cohort B (mCRPC): Composite response rate ^{[3][4]}
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End point description:

Composite response rate is defined as the investigator assessed radiological response by RECIST 1.1 for soft tissue and visceral lesions and Prostate Cancer Working Group 3 (PCWG3) for bone lesions, confirmed prostate specific antigen (PSA) decline of more than 50%, and/or confirmed circulating tumour cell [CTC] conversion from unfavorable (≥ 5 cells/7.5 ml blood) to favorable (< 5 cells). Evaluable for response set included all participants who were Molecularly Eligible Centrally Confirmed evaluable for response set with measurable disease at baseline and who received at least 1 dose of study intervention.

Due to an increased frequency and early onset of Grade ≥ 3 hematological toxicity noted among the participants receiving 240 mg of Ceralasertib, the sponsor decreased the dose to 160mg. Therefore, patients with the 240 mg BID starting dose were not included in the efficacy analyses for both study cohorts.

End point type	Primary
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End point timeframe:

Up to 2 years 4 months

Notes:

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

Justification: No formal hypothesis testing was conducted and therefore has not been presented here.

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

Justification: No formal hypothesis testing was conducted and therefore has not been presented here.

End point values	Cohort B (mCRPC): 160 mg of Ceralasertib			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Percentage of participants				
number (confidence interval 80%)	7.7 (0.8 to 26.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort A (aST): Duration of Radiological response (DoR)

End point title	Cohort A (aST): Duration of Radiological response (DoR) ^[5]
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End point description:

DoR is defined as the time from the date of first documented response (confirmed CR/PR) until date of documented progression or death in the absence of disease progression.

Molecularly eligible centrally confirmed evaluable for response set included all participants who were MolecularlyEligible Centrally Confirmed with measurable baseline disease and who received at least 1 dose of study intervention. The number of responders who subsequently progressed or died was 0, therefore, efficacy analysis was not conducted for Duration of response (DoR).

End point type	Secondary
End point timeframe:	
Up to 2 years 4 months	

Notes:

[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: No formal hypothesis testing was conducted and therefore has not been presented here.

End point values	Cohort A (aST): 160 mg of Ceralasertib			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[6]			
Units: Months				
median (inter-quartile range (Q1-Q3))	(to)			

Notes:

[6] - No subject was analyzed for Duration of Radiological response in Cohort A.

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort A (aST): Progression free survival (PFS)

End point title	Cohort A (aST): Progression free survival (PFS) ^[7]
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End point description:

PFS is defined as the time from start of study intervention until the date of objective disease progression or death (by any cause in the absence of progression) regardless of whether the participant withdraws from therapy or receives another anti-cancer therapy prior to progression.

Molecularly eligible centrally confirmed set included all participants who were Molecularly Eligible Centrally Confirmed and who received at least 1 dose of study intervention.

Due to an increased frequency and early onset of Grade≥3 hematological toxicity noted among the participants receiving 240 mg of Ceralasertib, the sponsor decreased the dose to 160mg. Therefore, patients with the 240 mg BID starting dose were not included in the efficacy analyses for both study cohorts.

End point type	Secondary
End point timeframe:	
Up to 2 years 4 months	

Notes:

[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: No formal hypothesis testing was conducted and therefore has not been presented here.

End point values	Cohort A (aST): 160 mg of Ceralasertib			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Months				
median (confidence interval 80%)	3.7 (1.9 to 5.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort A (aST): Percentage change in tumor size

End point title	Cohort A (aST): Percentage change in tumor size ^[8]
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End point description:

Percentage change in tumour size is defined as the reduction from baseline or the increase from baseline in the absence of a reduction in the sum of the longest diameters (or the short axis measurements for lymph nodes) of the target lesions. A negative change denotes a reduction in target lesion size. In the data presentation table, the arbitrary value 9.999, 9.9999 represents the data where data was not calculable as there were insufficient number of participants and the descriptive statistics cannot be calculated.

Molecularly eligible centrally confirmed evaluable for response set included all participants who were Molecularly Eligible Centrally Confirmed with measurable baseline disease and who received at least 1 dose of study intervention. Percentage change in tumor size was conducted every 8 weeks after the start of the treatment up to 1 year, then every 12 weeks until objective disease progression as per RECIST 1.1 or PCWG3 criteria.

End point type	Secondary
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End point timeframe:

Scan Visits 1 (Week 8), 2 (Week 16), 3 (Week 24), 4 (Week 32), 5 (Week 40), 6 (Week 48), 7 (Week 56)

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: No formal hypothesis testing was conducted and therefore has not been presented here.

End point values	Cohort A (aST): 240 mg of Ceralasertib	Cohort A (aST): 160 mg of Ceralasertib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	28		
Units: Percentage change				
arithmetic mean (standard deviation)				
Week 8 Cohort A: N= 23 Cohort B: N= 4	6.2 (± 10.99)	6.6 (± 22.45)		
Week 16 Cohort A: N= 13 Cohort B: N= 1	5.4 (± 9.9999)	-4.7 (± 16.83)		
Week 24 Cohort A: N= 10 Cohort B: N= 0	9.999 (± 9.9999)	-12.8 (± 21.47)		
Week 32 Cohort A: N= 5 Cohort B: N= 0	9.999 (± 9.9999)	-17.9 (± 34.41)		
Week 40 Cohort A: N= 1 Cohort B: N= 0	9.999 (± 9.9999)	-1.1 (± 9.9999)		
Week 48 Cohort A: N= 1 Cohort B: N= 0	9.999 (± 9.9999)	-100 (± 9.9999)		
Week 56 Cohort A: N= 1 Cohort B: N= 0	9.999 (± 9.9999)	-100 (± 9.9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort B (mCRPC): Percentage change in tumor size

End point title	Cohort B (mCRPC): Percentage change in tumor size ^[9]
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End point description:

Percentage change in tumour size is defined as the reduction from baseline or the increase from baseline in the absence of a reduction in the sum of the longest diameters (or the short axis measurements for lymph nodes) of the target lesions. A negative change denotes a reduction in target lesion size. Molecularly eligible centrally confirmed evaluable for response set included all participants who were Molecularly Eligible Centrally Confirmed with measurable baseline disease and who received at least 1 dose of study intervention. Percentage change in tumor size was conducted every 8 weeks after the start of the treatment up to 1 year, then every 12 weeks until objective disease progression as per RECIST 1.1 or PCWG3 criteria. Due to an increased frequency and early onset of Grade≥3 hematological toxicity on receiving 240 mg of Ceralasertib, the sponsor decreased the dose to 160mg. Therefore, patients with the 240 mg were not included in the efficacy analyses for both study cohorts.

End point type	Secondary
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End point timeframe:

Scan Visits 1 (Week 8), 2 (Week 16), 3 (Week 24), 4 (Week 32)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No formal hypothesis testing was conducted and therefore has not been presented here.

End point values	Cohort B (mCRPC): 160 mg of Ceralasertib			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Percentage change				
arithmetic mean (standard deviation)				
Scan Visit 1 (Week 8) N=8	2.0 (± 21.35)			
Scan Visit 2 (Week 16) N=4	-6.0 (± 9.37)			
Scan Visit 3 (Week 24) N=2	-1.4 (± 11.75)			
Scan Visit 4 (Week 32) N=2	-5.2 (± 13.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort A (aST) and B (mCRPC): Number of participants with serious and non-serious adverse events

End point title	Cohort A (aST) and B (mCRPC): Number of participants with serious and non-serious adverse events
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End point description:

The adverse events as a variable of safety and tolerability after administration of ceralasertib was determined. CTCAE= Common Terminology Criteria for Adverse Events; IP=investigational product

End point type	Secondary
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End point timeframe:

Up to 2 years 4 months

End point values	Cohort A (aST): 240 mg of Ceralasertib	Cohort A (aST): 160 mg of Ceralasertib	Cohort B (mCRPC): 240 mg of Ceralasertib	Cohort B (mCRPC): 160 mg of Ceralasertib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	30	1	15
Units: Participants				
All Adverse events (AE)	8	30	1	15
Any AE possibly related to treatment	8	21	1	13
Any AE of CTCAE Grade 3 or higher	6	15	1	8
Any AE of CTCAE grade 3 or higher, related to IP	4	6	1	5
Any AE with outcome of death	0	0	1	0
Any AE with outcome = death related to IP	0	0	1	0
Any SAE (including events with outcome = death)	6	4	1	4
Any SAE (events outcome =death) related to IP	3	2	1	1
Any SAE leading to discontinuation of IP	0	1	1	0
IP-related SAE leading to discontinuation	0	0	1	0
Any AE leading to discontinuation of IP	0	1	1	1
IP-related AE leading to discontinuation	0	0	1	1
Any AE leading to dose modification	4	10	1	5
Any AE leading to dose reduction	1	4	0	3
Any AE leading to dose interruption	4	7	1	3
Any AE leading to dosing cycle delays	1	0	0	1
Any other significant AEs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Screening (Day -28 to Day -1) Until Follow-up (30 days post last dose)

Adverse event reporting additional description:

Safety analysis consist of all participants who received at least 1 dose of study intervention.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	Cohort A (aST): 240 mg of Ceralasertib
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Reporting group description:

Participants with Ataxia telangiectasia mutated (ATM) altered Advanced solid tumour (aST) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Reporting group title	Cohort A (aST): 160 mg of Ceralasertib
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Reporting group description:

Participants with ATM-altered aST received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Reporting group title	Cohort B (mCRPC): 240 mg of Ceralasertib
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Reporting group description:

Participants with ATM-altered Metastatic castration-resistant prostate cancer (mCRPC) received 240 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Reporting group title	Cohort B (mCRPC): 160 mg of Ceralasertib
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Reporting group description:

Participants with ATM-altered mCRPC received 160 mg of ceralasertib twice daily from Day 1 to Day 14 of 28 days cycle.

Serious adverse events	Cohort A (aST): 240 mg of Ceralasertib	Cohort A (aST): 160 mg of Ceralasertib	Cohort B (mCRPC): 240 mg of Ceralasertib
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	4 / 30 (13.33%)	1 / 1 (100.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Investigations			
Platelet count decreased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			

subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
Lymphocyte count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
White blood cell count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
Pancytopenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (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
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 30 (3.33%)	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
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (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
Small intestinal obstruction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 30 (3.33%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
Hypoxia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash maculo-papular			

subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
Infections and infestations			
Device related infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (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
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (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
Sepsis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	1 / 30 (3.33%)	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
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (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			
Cohort B (mCRPC): 160 mg of Ceralasertib			
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 15 (26.67%)		

number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutrophil count decreased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
White blood cell count decreased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Device related infection			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Cohort A (aST): 240 mg of Ceralasertib	Cohort A (aST): 160 mg of Ceralasertib	Cohort B (mCRPC): 240 mg of Ceralasertib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	30 / 30 (100.00%)	1 / 1 (100.00%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 8 (50.00%)	8 / 30 (26.67%)	1 / 1 (100.00%)
occurrences (all)	4	8	2
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	7 / 30 (23.33%)	0 / 1 (0.00%)
occurrences (all)	0	7	0
Chest pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Facial pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
oedema peripheral			
subjects affected / exposed	2 / 8 (25.00%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Pain			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Mucosal discolouration			

subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Penile pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 8 (0.00%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 8 (25.00%)	3 / 30 (10.00%)	1 / 1 (100.00%)
occurrences (all)	2	3	2
Dyspnoea			
subjects affected / exposed	4 / 8 (50.00%)	4 / 30 (13.33%)	1 / 1 (100.00%)
occurrences (all)	5	5	2
Hypoxia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Pleural effusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Anxiety			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	1 / 1 (100.00%)
occurrences (all)	1	1	1
Investigations			
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Platelet count increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	2 / 8 (25.00%)	2 / 30 (6.67%)	1 / 1 (100.00%)
occurrences (all)	2	4	1
Neutrophil count decreased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	4 / 30 (13.33%)	0 / 1 (0.00%)
occurrences (all)	0	7	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 8 (25.00%)	3 / 30 (10.00%)	0 / 1 (0.00%)
occurrences (all)	2	5	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	3 / 30 (10.00%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	3 / 8 (37.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Palpitation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dysguesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 8 (12.50%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Peripheral sensory neuropathy			

subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Dysarthria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Sensory disturbance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 8 (12.50%)	3 / 30 (10.00%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 8 (75.00%)	8 / 30 (26.67%)	0 / 1 (0.00%)
occurrences (all)	8	10	0
Thrombocytopenia			
subjects affected / exposed	1 / 8 (12.50%)	6 / 30 (20.00%)	0 / 1 (0.00%)
occurrences (all)	1	8	0
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Lymph node pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Eye pain			

subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Periorbital oedema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Scleral haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	5 / 30 (16.67%)	1 / 1 (100.00%)
occurrences (all)	1	9	2
Constipation			
subjects affected / exposed	2 / 8 (25.00%)	7 / 30 (23.33%)	0 / 1 (0.00%)
occurrences (all)	2	7	0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	2 / 8 (25.00%)	9 / 30 (30.00%)	0 / 1 (0.00%)
occurrences (all)	2	9	0
Vomiting			
subjects affected / exposed	3 / 8 (37.50%)	5 / 30 (16.67%)	0 / 1 (0.00%)
occurrences (all)	3	6	0
Stomatitis			
subjects affected / exposed	1 / 8 (12.50%)	5 / 30 (16.67%)	0 / 1 (0.00%)
occurrences (all)	1	5	0
Nausea			
subjects affected / exposed	4 / 8 (50.00%)	13 / 30 (43.33%)	0 / 1 (0.00%)
occurrences (all)	5	14	0

Dysphagia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anorectal disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic cytolysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	3 / 30 (10.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pruritis			
subjects affected / exposed	0 / 8 (0.00%)	3 / 30 (10.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Skin mass			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Actinic keratosis subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Renal and urinary disorders			
Proteinuria subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 2	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	3 / 30 (10.00%) 3	0 / 1 (0.00%) 0
Bone pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 30 (0.00%) 0	0 / 1 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	3 / 30 (10.00%) 3	0 / 1 (0.00%) 0
Muscular weakness			

subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	1 / 1 (100.00%)
occurrences (all)	1	0	2
Pain in extremity			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Spinal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Oral fungal infection			
subjects affected / exposed	0 / 8 (0.00%)	2 / 30 (6.67%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
COVID-19			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Herpes simplex reactivation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Appetite disorder			

subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	2 / 8 (25.00%)	6 / 30 (20.00%)	1 / 1 (100.00%)
occurrences (all)	2	6	2
Dehydration			
subjects affected / exposed	1 / 8 (12.50%)	1 / 30 (3.33%)	1 / 1 (100.00%)
occurrences (all)	1	1	1
Hypercalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	3 / 30 (10.00%)	0 / 1 (0.00%)
occurrences (all)	1	4	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Folate deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 30 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	2 / 8 (25.00%)	4 / 30 (13.33%)	0 / 1 (0.00%)
occurrences (all)	2	8	0

Non-serious adverse events	Cohort B (mCRPC): 160 mg of Ceralasertib		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 15 (100.00%)		
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	5 / 15 (33.33%)		
occurrences (all)	5		
Asthenia			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Chest pain			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Facial pain			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Mucosal discolouration			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Penile pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Pelvic pain			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Dyspnoea			

subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Hypoxia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Dyspnoea exertional			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Investigations			
Weight decreased			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Platelet count increased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Platelet count decreased			

subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Neutrophil count decreased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
White blood cell count decreased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			

Contusion subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Palpitation subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Nervous system disorders			
Dysguesia subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2		
Dizziness subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2		
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Dysarthria subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Sensory disturbance subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Neuropathy peripheral subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Neuralgia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Headache			

subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 15 (40.00%)		
occurrences (all)	8		
Thrombocytopenia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Neutropenia			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Lymph node pain			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Eye disorders			
Eye pain			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Periorbital oedema			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Scleral haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Diarrhoea			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Stomatitis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	8 / 15 (53.33%)		
occurrences (all)	10		
Dysphagia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Melaena			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Anorectal disorder			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Hepatobiliary disorders			

Hepatic cytolysis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Hypertransaminasaemia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Skin and subcutaneous tissue disorders			
Dry skin subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Pruritis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Skin mass subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Rash subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Actinic keratosis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Renal and urinary disorders			
Proteinuria subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Pollakiuria subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Bone pain			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Musculoskeletal pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Muscular weakness			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Spinal pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Groin pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Infections and infestations			
Oral fungal infection			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
COVID-19			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Herpes simplex reactivation			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Rhinitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Device related infection			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Skin infection			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	3 / 15 (20.00%)		
occurrences (all)	3		
Dehydration			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		

Hyperglycaemia			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Hyperphosphataemia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Folate deficiency			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Hyponatraemia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 August 2020	In the amendment 1, the test "discontinuation" was added to the table title, definition of prolonged Grade 2 toxicity, the text "Grade 2" for thrombocytopenia under Grade 2 events and addition of Grade 3-4 neutropenia or Grade 4 anaemia" under Grade 3-4 toxicity were added.
04 November 2022	This amendment is considered to be substantial based on the criteria set forth in Article 10(a) of Directive 2001/20/EC of the European Parliament and the Council of the European Union. In Section 6.1 (Intervention after the final DCO) and Section 11.6.7 (Intervention after the Final DCO) text was added to clarify options for continuation of treatment for patients receiving benefit at time of final DCO.
27 May 2024	New section/text related to study disruption, clarification of sample size following dose reduction to 160 mg BID in the synopsis, Update following dose reduction to 160 mg BID in the schema, to provide clarification for ATM mutation definition in Appendix K.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported